Cochrane Library

Cochrane Database of Systematic Reviews

Patient navigator programmes for children and adolescents with chronic diseases (Review)

Lalji R, Koh L, Francis A, Khalid R, Guha C, Johnson DW, Wong G

Lalji R, Koh L, Francis A, Khalid R, Guha C, Johnson DW, Wong G.
Patient navigator programmes for children and adolescents with chronic diseases.
Cochrane Database of Systematic Reviews 2024, Issue 10. Art. No.: CD014688.
DOI: 10.1002/14651858.CD014688.pub2.

www.cochranelibrary.com

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

WILEY

TABLE OF CONTENTS

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

[Intervention Review]

Patient navigator programmes for children and adolescents with chronic diseases

Rowena Lalji[1,2,3], Lee Koh[4], Anna Francis[1,2,3], Rabia Khalid[5], Chandana Guha[5], David W Johnson[2], Germaine Wong[6]

[1]The Centre for Kidney Research, The University of Queensland, Brisbane, Australia. [2]Metro South Kidney and Transplant Services, Princess Alexandra Hospital, Woolloongabba, Australia. [3]Queensland Children and Adolescent Renal Service (QCARS), Queensland Children's Hospital, Brisbane, Australia. [4]Department of Paediatric Nephrology, Starship Children's Hospital, Auckland, New Zealand. [5]School of Public Health, The University of Sydney, Sydney, Australia. [6]Centre for Kidney Research, The Children's Hospital at Westmead, Westmead, Australia

Contact: Rowena Lalji, rowena.lalji@health.qld.gov.au.

Editorial group: Cochrane Central Editorial Service.
Publication status and date: New, published in Issue 10, 2024.

Citation: Lalji R, Koh L, Francis A, Khalid R, Guha C, Johnson DW, Wong G. Patient navigator programmes for children and adolescents with chronic diseases. *Cochrane Database of Systematic Reviews* 2024, Issue 10. Art. No.: CD014688. DOI: 10.1002/14651858.CD014688.pub2.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Despite a substantial global improvement in infant and child mortality from communicable diseases since the early 1990s there is now a growing burden of chronic disease in children and adolescents worldwide, mimicking the trend seen in the adult population. Chronic diseases in children and adolescents can affect all aspects of their well-being and function with these burdens and their health-related consequences often carried into adulthood. Up to one third of disability-adjusted life years for children and adolescents globally are a result of chronic disease. This has profound implications for the broader family unit, communities, and health systems in which these children and young people reside.

Models of chronic care delivery for children and adolescents with chronic disease have traditionally been adapted from adult models. There is a growing recognition that children and adolescents with chronic diseases have a unique set of healthcare needs. Their needs extend beyond disease education and management appropriate to the developmental stage of the child, to encompass psychological well-being for the entire family and a holistic care approach focusing on the social determinants of health. It is for this reason that patient navigators have been proposed as a potential intervention to help fulfil this critical healthcare gap.

Patient navigators are trained medical or non-medical personnel (e.g. lay health workers, community health workers, nurses, or people with lived experience) who provide guidance for the patients (and their primary caregivers) as they move through complex (and often bewildering) medical and social systems. The navigator may deliver education, help to co-ordinate patient care, be an advocate for the patient (and their primary caregivers), or combinations of these. Patient navigators can assist people with a chronic illness (especially those who are vulnerable or from a marginalised population, or both) to better understand their diagnoses, treatment options, and available resources. As there is considerable variation in the purpose, design, and target population of patient navigator programmes, there is a need to systematically review and summarise the existing literature on the effectiveness of navigator programmes in children and young adults with chronic disease.

Objectives

To assess the effectiveness of patient navigator programmes in children and adolescents with chronic diseases.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Search methods

We searched the Cochrane Library and Epistemonikos up to 20 January 2023 for related systematic reviews using search terms relevant to this review. We searched CENTRAL, MEDLINE, Embase, CINAHL EBSCO, conference proceedings, the International Clinical Trials Register (ICTRP) Search Portal, and ClinicalTrials.gov for primary studies.

Selection criteria

We included randomised controlled trials reporting the effect of patient navigator interventions on children and adolescents (aged 18 years or younger) with any chronic disease in hospital or community settings. Two review authors independently assessed the retrieved titles and abstracts, and where necessary, the full text to identify studies that satisfied the inclusion criteria.

Data collection and analysis

Two review authors extracted data using a standard data extraction form. We used a random-effects model to perform a quantitative synthesis of the data. We used the I^2 statistic to measure heterogeneity amongst the studies in each analysis. We indicated summary estimates as mean differences (MD), where studies used the same scale, or standardised mean differences (SMD), where studies used different scales, with 95% confidence intervals (CI). We used subgroup and univariate meta-regression to assess reasons for between-study differences. We used the Cochrane RoB 1 tool to assess the methodological quality of the included studies. We used GRADE to assess the certainty of the evidence.

Main results

We included 17 studies (2895 randomised participants). All studies compared patient navigators with standard care. Most studies were at unclear or high risk of bias. Meta-analysis was undertaken only for those studies that had the same duration of patient navigator intervention and follow-up/reporting of outcome measures.

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on self-reported quality of life of children with chronic illness (SMD 0.63, 95% CI −0.20 to 1.47; I^2 = 96%; 4 studies, 671 participants; very low-certainty evidence); parent proxy-reported quality of life (SMD 0.09, 95% CI −2.21 to 2.40; I^2 = 99%; 2 studies, 309 participants; very low-certainty evidence); or parents' or caregivers' quality of life (SMD −1.98, 95% CI −4.13 to 0.17; I^2 = 99%; 3 studies, 757 participants; very low-certainty evidence). It is uncertain whether duration of patient navigator intervention accounts for any of the variances in the changes in quality of life.

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on the number of hospital admissions (MD −0.05, 95% CI −0.34 to 0.23; I^2 = 99%; 2 studies, 381 participants; very low-certainty evidence) and the number of presentations to the emergency department (MD 0.06, 95% CI −0.23 to 0.34; I^2 = 98%; 2 studies, 381 participants; very low-certainty evidence). Furthermore, it is unclear whether patient navigator programmes reduce the number of missed school days as data were sparse (2 studies, 301 participants).

Four studies (629 participants) reported data on resource use. However, given the variation in units of analysis used, meta-analysis was not possible (very low-certainty evidence). All studies reported cost savings or quality-adjusted life year improvement (or both) in the patient navigation arm.

No studies reported on adverse events (specifically, abuse of any type against the navigator, the patient, or their family members).

Authors' conclusions

There is insufficient evidence at present to support the use of patient navigator programmes for children and adolescents with chronic diseases. The current evidence is based on limited data with very low-certainty evidence. Further studies are likely to significantly change these results.

PLAIN LANGUAGE SUMMARY

What are the benefits and harms of patient navigation for children and adolescents with chronic diseases?

Key messages

– We are very uncertain about the effects of patient navigator programmes compared with usual care on the quality of life of children and adolescents; the quality of life of their families; how many times they are admitted to hospital or go to the emergency department; how many school, day care, or college days they miss; and how much this costs.

– There is currently a lack of evidence to determine the effects of patient navigator programmes on children and adolescents with chronic diseases and further well-designed studies are recommended.

What is the issue?

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

The burden of chronic (long-lasting) diseases is growing in children and adolescents worldwide. Chronic diseases affect all aspects of a child's well-being including their growth; when they achieve milestones; how well they learn, remember, and use information; and how they manage and control their emotions. This can be carried into adult life. A child with a chronic disease also has a significant impact upon their family.

Health systems are searching for novel, low-cost ways to help improve chronic health outcomes for children and adolescents with chronic illnesses. One such option is the use of patient navigators.

What are patient navigators?

Patient navigators are trained medical or non-medical workers who help to guide and navigate patients and their families through complex medical systems by helping to co-ordinate patient care, give education, and work as an advocate for patients and their families. Patient navigators have been shown to help adults throughout their healthcare pathway. However, their benefits to children and adolescents with chronic diseases are unknown.

What did we want to find out?

We wanted to know if patient navigators are beneficial to children and adolescents with chronic diseases compared with usual care (that is, the routine care received by patients for prevention or treatment of diseases).

What did we do?

We search for studies comparing patient navigators with usual care to see if they improved the lives of children and adolescents with chronic diseases.

What did we find?

We found 17 studies enroling 2895 children and adolescents with illnesses such as asthma (a common lung condition that causes breathing difficulties), type 1 diabetes mellitus (high blood sugar), sickle cell disease (a disease that affects the shape of red blood cells), multiple medical needs, and conditions caused by being born too early in pregnancy. Studies varied widely in the duration, type, and frequency of patient navigator programmes as well as how long they were monitored for, which made it difficult to compare results.

The evidence is very uncertain about the effects of patient navigator programmes compared with usual care on the quality of life of children/adolescents or their carers; the number of times they were admitted to hospital or visited an emergency department; days of school/daycare/college missed; and use of healthcare facilities and resources.

What are the limitations of the evidence?

Our confidence in the evidence is very low because studies had poor methods, not all the studies provided data about everything that we were interested in, and they used different ways of measuring results.

How up to date is this evidence?

The evidence is current to 20 January 2023.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

SUMMARY OF FINDINGS

Summary of findings 1. Patient navigators compared to standard care for children and adolescents with chronic diseases

Patient navigator compared to standard care for children and adolescents with chronic diseases

Patient or population: children and adolescents with chronic diseases
Setting: hospital (outpatient) and community
Intervention: patient navigator
Comparison: standard care

Outcomes	Effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
Child QoL – self-reported at 12 months of care (either standard or patient navigator)	**SMD 0.63 higher in favour of patient navigator group** (0.20 lower to 1.47 higher)	671 (4 studies)	⊕⊖⊖⊖ **Very low**[a]	Higher score indicated an improvement in QoL.
Child QoL – parent proxy-reported at 12 months of care (either standard or patient navigator)	**SMD 0.09 higher in favour of patient navigator group** (2.21 lower to 2.40 higher)	309 (2 studies)	⊕⊖⊖⊖ **Very low**[b]	Higher score indicated an improvement in QoL.
Parent QoL at 24 months of care (either standard or patient navigator)	**SMD 1.98 lower in favour of control group** (4.13 lower to 0.17 higher)	757 (3 studies)	⊕⊖⊖⊖ **Very low**[c]	Higher score indicated an improvement in QoL.
Abuse of any type (against patient navigator, child, or family)	—	—	—	Not reported by any study.
Hospitalisation rates during 12 months of care (either standard or patient navigator)	**MD 0.05 lower in favour of control group** (0.34 lower to 0.23 higher)	381 (2 studies)	⊕⊖⊖⊖ **Very low**[d]	Higher score indicated reduction in hospitalisation rates.
Rates of emergency department attendance during 12 months of care (either standard or patient navigator)	**MD 0.06 higher in favour of patient navigator group** (0.23 lower to 0.34 higher)	381 (2 studies)	⊕⊖⊖⊖ **Very low**[e]	Higher score indicated reduction in emergency department presentations.
Resource use	See comment	629 (4 studies)	⊕⊖⊖⊖ **Very low**[g]	Due to heterogeneity of each study's unit of analysis, meta-analysis not possible. Each study reported a cost benefit or a quality-adjusted life year improvement, or both (Carter 2022 as part of Frakking 2022; Flores 2009; Karnick 2007; Weinstein 2021).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Days of school, college, daycare missed	See comment	301 (2 studies)	⊕⊖⊖⊖ **Very low**[f]	Due to heterogeneity of each study's units of analysis, meta-analysis not possible. Both studies reported a reduction in school days missed (Flores 2009; Frakking 2022).

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **QoL:** quality of life; **SMD:** standardised mean difference.

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a] Downgraded three levels due to serious limitations in study or execution (risk of bias – differences at baseline for between control and intervention groups in Katz 2014 and Looman 2015, 48.7% of control participants in Weinstein 2021 failed to complete an initial education session) (or both); inconsistency of results (heterogeneity); indirectness (use of Parent Kessler Distress Score and Patient Health Questionnaire to assess quality of life) and imprecision (95% CI −0.20 to 1.47).
[b] Downgraded three levels due to serious limitations in study design or execution (or both); inconsistency; imprecision; indirectness (use of Parent Kessler Distress Score and Patient Health Questionnaire to assess quality of life); and risk of bias (e.g. differences at baseline for Katz 2014 and 48.7% of control participants in Weinstein 2021 failed to complete an initial education session).
[c] Downgraded three levels due to serious limitations in study design or execution (or both); indirectness (use of Children's Depression Inventory 2 as an indirect measure of quality of life); inconsistency; imprecision; and risk of bias (e.g. large attrition rates and almost 50% of intervention group did not have support services in Ye 2013).
[d] Downgraded three levels due to serious methodological limitations in study design or execution (risk of bias) (or both); inconsistency of results (heterogeneity); and imprecision (95% CI −0.34 to 0.23) (e.g. undercapture of emergency department data in Looman 2015 and incentive payments and large attrition bias in Flores 2009).
[e] Downgraded three levels due to serious limitations in study design or execution (or both); inconsistency; imprecision; and risk of bias (e.g. under-reporting of emergency department data for Looman 2015 and incentive payments for Flores 2009).
[f] Downgraded three levels due to inconsistency in the results in both Flores 2009 and Frantatoni 2022; imprecision; and limitations in study design or execution (or both) in Flores 2009; and imprecision in Frantatoni 2022.
[g] Downgraded three levels due to methodological limitations in study design or execution (or both) (Flores 2009; Karnick 2007; Weinstein 2021); indirectness of evidence (Flores 2009; Karnick 2007; Weinstein 2021); and publication bias.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

BACKGROUND

Description of the condition

Chronic diseases are broadly defined as persisting, non-communicable health conditions (physical or mental), which can impact upon a person's ability to function from a physical, cognitive, or social perspective. Although not immediately life-threatening, these conditions require long-term medical care or related services (Australian Institute of Health and Welfare 2020; CDC 2021).

Chronic disease represents a high cost, resource-intensive subset of disease burden, which by 2020 is predicted to account for 73% of all deaths, and 60% of the worldwide burden of adult disease (WHO 2019). Mirroring the trend seen in adults, the prevalence of chronic disease within the paediatric population is increasing with time (Global Burden of Disease 2019; Kuenzig 2022; Perrin 2014; Stoll 2010; van Cleave 2010). An estimated one in four children is affected by at least one chronic disease, with some evidence to suggest this rate is even higher when accounting for both sex and ethnicity (van Cleave 2010; Wijlaars 2016).

Children and adolescents represent a particularly vulnerable cohort, with unique healthcare requirements that are different from those of their adult counterparts (WHO 2018). Depending on the chronic disease, children have been shown to have increased mortality (up to 30 times in kidney failure (McDonald 2004)), and morbidity, including reduced self-reported quality of life, neurocognitive impairment, and appreciably higher rates of depression and anxiety (Bennett 1994; Bregnballe 2007; Francis 2019; Quittner 2008). Often, these burdens (and their health-related consequences) are carried into adulthood (Cohen 2018). Furthermore, the diagnosis and management of chronic childhood disease has significant financial, emotional, and psychological ramifications for the broader family unit (Lähteenmäki 2004; Medway 2015; Tsai 2006).

Social determinants of health play a significant role in chronic disease outcomes for children, particularly within socially disadvantaged families and minority communities (Council on Community Pediatrics 2016; Marmot 2012; Wilson 2019). With continued gaps in chronic disease management, and persistent fragmentation in the healthcare system, medical professionals, policymakers, and relevant stakeholders are seeking new, cost-effective strategies to overcome modifiable barriers to accessing appropriate chronic disease care for children, and thus, improve their overall health outcomes.

Description of the intervention

The intervention for this review was patient navigators. Patient navigators are trained medical or non-medical personnel (e.g. lay health workers, community health workers, nurses, care co-ordinators, or people with lived experience), who provide guidance for the children (and their primary caregivers, such as parents or guardians), as they move through the complex medical and social systems (Carter 2018; Kelly 2015). The navigator may deliver education, help to co-ordinate care, or be an advocate for the child (and their primary caregivers) who are disadvantaged from a social, cultural, or economic perspective (or combinations of these). Notably, there is variability and overlap with programmes of different names, within different health economies, when describing the patient navigator role in the literature (Dohan 2005). It is generally accepted that the patient navigator helps to navigate people through existing services, in contrast to case managers, who may also act as care providers (e.g. to provide psychosocial care (Kelly 2019)).

It has been shown that patient navigators improve health outcomes for adults with chronic diseases, particularly in the realm of cancer (Freeman 2005; Rodriguez-Torres 2019; Wells 2008), and diabetes (Spencer 2018; Thom 2013), by helping them overcome both individual and systemic barriers, and access timely and appropriate medical care. For young children specifically, the role of the patient navigator is for the most part, to support and empower the family unit (rather than the children themselves), so that they can better understand the health requirements of their children, and how best to obtain this within the constraints of the health system that is available to them (Smith 2017). In adolescents, although the patient navigator's focus largely shifts to the young person's unmet healthcare needs, it is acknowledged that they, too, may be best served by addressing the needs of the family unit (Chu 2015).

How the intervention might work

The fundamental role of the patient navigator is to help guide and proactively support people with a health problem (and their primary caregivers) to traverse the often bewildering, complex maze of the healthcare, social care, and education systems, by enhancing the lines of communication, and providing a single point of contact (Kelly 2015). By identifying and matching a person's unmet needs to the appropriate resources, the aim of the patient navigator is to improve access to and decrease the fragmentation of care to achieve optimal outcomes for people with a health concern (Mackie 2018; Smith 2017). The patient navigator can be of particular assistance to vulnerable and marginalised populations with chronic illnesses, to help them better understand their diagnoses, treatment options, and available resources (Natale-Pereira 2011; Pantell 2020). Distrust and fear of healthcare services, secondary to different cultural, language, or health beliefs, can also contribute to delays in seeking treatment, and high rates of non-adherence (Feinberg 2016; Natale-Pereira 2011; Petereit 2008). Patient navigators are ideally positioned to foster trust within these marginalised and minority communities (Rodriguez-Torres 2019).

Given the broad cognitive and development spectrum of the paediatric population, the primary target of the patient navigator role as an intervention will also differ. For young children and adolescents with developmental delays, providing health guidance and support to the primary caregivers is intended, in turn, to have a positive effect on the health outcomes of the family as a unit. For adolescents, the patient navigator supports and empowers the family unit and the young person themselves, in preparation for the inevitable transition to adult services (Callahan 2001; Chu 2015). Ideally, early and appropriate health engagement for all children should improve their health outcomes, and reduce, if not prevent entirely, both the short- and long-term complications of their chronic diseases.

Why it is important to do this review

Despite the growing worldwide popularity of this style of intervention, the evidence for the role of patient navigators in the health care of young people is heterogeneous in the populations studied (young children versus adolescents), the way patient

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

navigators have been utilised (e.g. type and setting of intervention), and in the outcome measures reported (e.g. self-reported by the young person versus reported by carer) (Desveaux 2019; McBrien 2018). Whilst some studies have reported improvements in quality of life scores reported by the young person and the carer (Gottlieb 2016; Krieger 2009), reduced presentations to the hospital or emergency department (Morgan 2013; Pantell 2020), and a health economic cost benefit (Jandorf 2013), other studies have found no difference in either clinical or self-reported outcomes (Caskey 2019; Resnick 2009; Simon 2017). There have also been reports of harm in adults, in the form of their discomfort with the gender or cultural mismatch of the patient navigator and their intervention (Carroll 2010). It is currently unclear whether children and adolescents with chronic diseases, under the care of a patient navigator programme, have better or equivalent health outcomes compared with those receiving standard care.

OBJECTIVES

To assess the effectiveness of patient navigator programmes in children and adolescents with chronic diseases.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials of both individual and cluster design. If cross-over studies were available, we used data from the first period of these studies. We included full-text studies, conference abstracts, and unpublished data. We included studies irrespective of their publication status and language of publication.

Types of participants

We included all children and adolescents diagnosed with any chronic diseases requiring ongoing medical care.

For this review, we defined children as those aged 0 to 18 years, inclusive (WHO 2020).

We included studies that contained a subset of relevant participants (e.g. both adults and children) only if the study reported separate data for the eligible selection of the population (allowing data from the eligible participants to be included in the review), or if the majority of the participants in the study were aged 18 years or younger. We documented difficult decisions regarding inclusion or exclusion of specific studies in the review.

Types of interventions

We used the following definition for a patient navigator: "… a trained medical or nonmedical person who assists people with chronic conditions to traverse complex health systems. PNs [patient navigator] help people (particularly vulnerable and disadvantaged populations) to understand their diagnosis, treatment options, available resources, and provide a crucial link to overcome both individual and systemic barriers to healthcare access" (Natale-Pereira 2011).

The patient navigator role is sometimes interchangeably referred to in the literature as that of a community health worker, navigator, health advocate, case manager, or care co-ordinator (Kelly 2019). Two review authors (RL and JK) independently considered studies that use these terms (or variations thereof) provided their role and function within the study fulfilled the patient navigator definition listed above. In cases of discordance, we consulted a third review author (CG).

Inclusion criteria

- We included trials comparing a patient navigator intervention with current standard of care (e.g. no patient navigator), as well as trials with active comparison groups.
- Patient navigator programmes may have been either hospital or community based.

Exclusion criteria

- Studies focused on health coaches as the primary intervention of focus. The role of the patient navigator is distinctly different from a health coach, who focusses specifically on the person's behaviour change, by encouraging the development of sustainable healthy behaviours and attitudes in the people with whom they work, for chronic disease management and prevention (Conn 2019).

We did not exclude studies on the basis of outcomes reported, and we included studies that did not contain any outcome data.

Types of outcome measures

Primary outcomes

- **Quality of life (self-reported or parent proxy-report)**, or self-reported health status, assessed in any way. For young children, or children who had developmental delays, this was likely to be a proxy-report, given by the primary caregivers, 12 and 24 months after the start of the intervention. Accepted quality of life scales or self-reported health status were; Pediatric Quality of Life Inventory, Therapeutics Group Child Asthma Short Form, Quality of Life Scale for Children (QoL-C), Child Health Related Quality of Life (Child HRQL) scale, Health Related Quality of Life (HRQL) scale, Psychosocial Quality of Life (Psychosocial QL), and Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ)
- **Caregiver health, functioning, and quality of life**, 12 and 24 months after the start of intervention (either standard care or patient navigator), assessed in any way
- **Abuse of any type** against the young person, the siblings, family, or the patient navigator (physical, emotional, mental, or sexual)

Secondary outcomes

- **Hospitalisation rates**, measured at 12 and 24 months after the start of intervention (either standard care or patient navigator), defined as number of admissions per year
- **Rates of emergency department attendance** measured at 12 and 24 months after the start of intervention (either standard care or patient navigator), defined as number of visit per year
- **Resource use**, defined using healthcare staff time, resource facilities, consumables, or cost for the duration of the intervention
- **Days of school, college, daycare missed**

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Search methods for identification of studies

Electronic searches

The Effective Practice and Organisation of Care group Information Specialist developed the search strategies in consultation with the review authors.

We searched the Cochrane Library and Epistemonikos (www.epistemonikos.org) for related systematic reviews. We searched the following databases for primary studies, from inception to the date of search.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2022, Issue 12), in the Cochrane Library
- MEDLINE Ovid (1946 to 20 January 2023)
- Embase Ovid (1974 to 31 July 2021), Embase Elsevier (1 January 2021 to 20 January 2023)
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1982 to 20 January 2023)

Search strategies comprised keywords and controlled vocabulary terms (see Appendix 1). We did not apply any limits on language, and we searched all databases from inception to the date of search. We used a methodology search filter to limit retrieval to appropriate study designs.

Searching other resources

Trial registries

- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; www.who.int/ictrp; to 20 January 2023).
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; to 20 January 2023).

Grey literature

We searched the grey literature to identify studies not indexed in the databases listed above.

- UK National Institute for Health Research (NIHR; www.nihr.ac.uk; to 20 January 2023)
- Health Research Board (HRB; www.hrb.ie; to 20 January 2023)
- National Institute for Health and Care Excellence (NICE; www.nice.org.uk; to 20 January 2023)

We reviewed reference lists of all included studies and relevant systematic reviews for additional potentially eligible primary studies. We contacted authors of included studies and reviews to clarify reported published information, and to seek unpublished results and data. We contacted researchers with expertise relevant to the review topic and Effective Practice and Organisation of Care interventions. We conducted cited reference searches for all included studies in ISI Web of Knowledge, and screened individual journals (e.g. handsearched *JAMA Pediatrics*, *Archives of Disease in Childhood*, and *Lancet Paediatrics*).

We provided appendices for all strategies used, including a list of sources screened and relevant reviews and primary studies reviewed. See Appendix 1 for the search strategies employed.

Data collection and analysis

Selection of studies

We downloaded all titles and abstracts, retrieved by electronic searching, to a reference management database and removed duplicates. Two review authors (RL and LK) independently screened titles and abstracts for inclusion. We retrieved the full-text study reports or publication, and two review authors (RL and LK) independently screened the full text, identified studies for inclusion, and identified and recorded reasons for exclusion of the ineligible studies. We resolved any disagreement through discussion, or, if required, we consulted a third review author (GW).

We listed studies that initially appeared to meet the inclusion criteria, but that we later excluded, in the Characteristics of excluded studies table. We collated multiple reports of the same study, so that each study, rather than each report, was the unit of interest in the review. We also provided any information we could obtain about ongoing studies. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009).

Data extraction and management

We used the Effective Practice and Organisation of Care standard data collection form, and adapted it for study characteristics and outcome data (EPOC 2017a); we piloted the form on one study in the review (Spaic 2019). We reviewed the economic evidence (including reported resource use) reported in the trials and assessed the efficacy of the intervention of interest based on the Johanna Briggs Evidence of Implementation reporting guidelines (Gomersall 2015). Two review authors (RL and LK) independently extracted the following study characteristics from the included studies, and entered the data into Review Manager (RevMan 2024).

- Methods: study design, number of study centres and location, study setting, withdrawals, date of study, follow-up
- Participants: number, mean age, age range, sex, ethnicity, chronic disease diagnosis, diagnostic criteria, inclusion criteria, exclusion criteria, other relevant characteristics
- Interventions: intervention components, comparison, fidelity assessment
- Outcomes: main and other outcomes specified and collected, time points reported
- Notes: funding for trial, notable conflicts of interest of trial authors, ethical approval

Two review authors (RK and LK) independently extracted outcome data from the included studies. We noted in the Characteristics of included studies table if outcome data were reported in an unusable way. We resolved disagreements by consensus, or by involving a third review author (GW).

Assessment of risk of bias in included studies

Two review authors (RL and LK) independently assessed risk of bias for each study using the Cochrane RoB 1 tool, the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* Section 8.5 (Higgins 2011), and guidance from the Effective Practice and Organisation of Care group (EPOC 2017b). We resolved any disagreements by discussion, or by involving a third review author (GW). We assessed the risk of bias according to the following domains.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

- Random sequence generation
- Allocation concealment
- Blinding of participants and personnel
- Blinding of outcome assessment
- Incomplete outcome data
- Selective outcome reporting
- Baseline outcomes measurement
- Baseline characteristics
- Other bias, including contamination (e.g. participants from the same family in different treatment arms), null bias due to poorly delivered intervention of too broad inclusion criteria, post hoc intensification of intervention.

We judged each potential source of bias as high, low, or unclear, and provided a quote from the study report together with a justification for our judgement in the risk of bias table. We summarised the risk of bias judgements across different studies for each of the domains listed. We assigned an overall risk of bias assessment (high, moderate, or low) for each of the included studies, using the approach suggested in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We considered studies with low risk of bias for all key domains (namely, blinding of outcome assessment, incomplete outcome data, and selective reporting), or where it seems unlikely that bias might seriously alter the results, to have a low risk of bias. We considered studies in which the risk of bias in at least one domain was unclear, or judged to have some bias that could plausibly raise doubts about the conclusions, to have an unclear risk of bias. We considered studies with a high risk of bias in at least one domain, or judged to have serious bias that decreases the certainty of the conclusions, to have a high risk of bias.

We considered blinding separately for different key outcomes, when necessary (e.g. for unblinded outcome assessment, risk of bias for caregiver health may be very different from for a patient's reported pain scale). When information on risk of bias related to unpublished data or correspondence with a trialist, we noted this in the risk of bias table.

We did not exclude studies on the grounds of their risk of bias, but clearly reported the risk of bias when presenting the results of the studies.

When considering treatment effects, we considered the risk of bias in the studies that contributed to that outcome.

Measures of treatment effect

We estimated the effect of the intervention using risk ratio or risk difference for dichotomous data, together with the appropriate associated 95% confidence interval (CI), and mean difference (MD), where studies used the same scale, or standardised mean difference (SMD), where studies used different scales, for continuous data, together with the 95% CI (Higgins 2020a). We ensured that an increase in scores for continuous outcomes could be interpreted in the same way for each outcome, explained the direction to the reader, and reported when we reversed the directions, where necessary.

Unit of analysis issues

We included studies with a cluster design (e.g. where groups of individuals, rather than individuals, were randomised to different interventions) where the unit of allocation was the cluster or group. If we included studies with a cluster design, we attempted to determine if the authors of these studies appropriately controlled for clustering effects in their analysis, to avoid a unit of analysis error (Whiting-O'Keefe 1984). If there was doubt, we contacted the authors for clarification. If cluster studies were appropriately analysed to account for clustering in the data, we extracted direct measures of effect, where available, and used them in the meta-analyses, using the generic inverse-variance method.

We included the first period of data only from cross-over studies if these were available.

Dealing with missing data

We contacted investigators to verify key study characteristics, and obtain missing outcome data when possible (e.g. when a study was identified as abstract only). We tried to compute missing summary data from other reported statistics. Whenever it was not possible to obtain data, we reported the level of missingness, and considered how that might impact the certainty of the evidence.

Assessment of heterogeneity

If we found a sufficient number of studies, for which we judged participants, interventions, comparisons, and outcomes to be sufficiently similar, we conducted a meta-analysis (Borenstein 2009). In each analysis, we used the I^2 statistic to measure heterogeneity amongst the trials. An approximate guide to interpretation in the context of meta-analyses of randomised trials was as follows.

- 0% to 40%: might be important
- 30% to 60%: may represent moderate heterogeneity[a]
- 50% to 90%: may represent substantial heterogeneity[a]
- 75% to 100%: considerable heterogeneity[a]

[a] The importance of the I^2 statistic depends on the magnitude and direction of effects, and the strength of evidence of heterogeneity (e.g. P value from the Chi^2 test, or a CI for the I^2 statistic: uncertainty in the value of the I^2 statistic is substantial when the number of studies is small) (Higgins 2020a). If we identified substantial heterogeneity (50% to 90%), we explored it with prespecified subgroup analyses.

Assessment of reporting biases

We attempted to contact study authors to request missing outcome data. When this was not possible, and the missing data were thought to introduce serious bias, we explored the impact of including such studies in the overall assessment of results. If we had been able to pool more than 10 trials, we planned to create and examine a funnel plot to explore possible publication biases, interpreting the results with caution (Sterne 2011).

Data synthesis

We undertook meta-analyses only when this was meaningful (i.e. if the treatments, participants, and the underlying clinical question were similar enough for pooling to make sense) (Borenstein

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

2009). A common way that trialists indicate they have skewed data is by reporting medians and interquartile ranges. When we encountered this, we noted that the data were skewed and considered the implications of this. Where a trial reported multiple arms, we included only the relevant arms. If two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) had to be entered into the same meta-analysis, we combined the intervention groups to create a single pair-wise comparison as per Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020b).

If it was not possible to undertake a quantitative synthesis of the results, we undertook non-quantitative synthesis using the most appropriate, acceptable alternative option (summarising effect estimates, combining P values, or vote counting based on direction of effect) suggested in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020a).

Subgroup analysis and investigation of heterogeneity

For this review, if there was heterogeneity in a sufficient number of studies that had similar outcomes and comparison groups, we planned to perform a subgroup analysis for the following factors, which may potentially moderate the effect of the intervention.

- Age: divided into children (zero years to nine years, inclusive) and adolescents (10 years to 18 years, inclusive) (WHO 2020). We hypothesises that patient navigator effects will be more pronounced in young children, given that the intervention in this age group will more likely target the family as a unit (rather than the child as an individual).
- Ethnicity: divided into minority versus non-minority groups (minority groups were defined as a minority group for the region or country in which the study was undertaken). Minority groups (including Indigenous people) are a vulnerable cohort who were more likely to belong to a lower socioeconomic group, have poorer health literacy, and experience language and cultural barriers; these affect their access to appropriate and timely health care (Natale-Pereira 2011). For this reason, we hypothesised that this subgroup may be more responsive to a patient navigator intervention.
- Cancer versus non-cancer diagnosis: we hypothesised that children and adolescents with a cancer diagnosis generally have significant healthcare burdens, which require multiple specialist medical reviews, and intensive in-hospital care. These young people may experience larger benefit from a patient navigator than a young person with a non-cancer diagnosis.
- Care setting for patient navigator intervention (hospital versus community).
- Traditional versus non-traditional family units (traditional refers to a nuclear family, and non-traditional incorporates all other variations).
- Sex of the patient.

We planned to apply a test for interaction to test for differences between subgroups.

We planned to perform meta-regression if there were sufficient studies for a meta-analysis.

Sensitivity analysis

We conducted the following sensitivity analyses to assess the robustness of our conclusions and explore their impact on effect sizes.

- Restricting the analysis to published studies
- Restricting the analysis to studies with a low risk of bias

Stakeholder consultation and involvement

Chandana Guha (CG) is a consumer representative and research assistant at the Centre for Kidney Research (Westmead, Sydney) and is currently enroled as a PhD student at the University of Sydney. CG is also the mother of a child with a serious chronic disease and has over 25 years of experience navigating complex health systems. She provided first-hand insight into what families and consumers value. CG was involved in the conception and drafting of the study protocol and played an active part of the systematic review.

Summary of findings and assessment of the certainty of the evidence

Two review authors independently assessed the certainty of the evidence (high, moderate, low, and very low), using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias (Guyatt 2008)). We graded our top seven outcomes of interests (see list below). We assessed blinding using the Cochrane RoB 1 tool. We acknowledged some of our outcomes are likely to be 'subjective'. In that case, we considered the lack of outcome assessment blinding as high risk of bias.

We used methods and recommendations described in Section 8.5 of the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2011), Chapter 14 of the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2020a), the EPOC worksheets (EPOC 2017c), and GRADEpro GDT software (GRADEpro GDT). We resolved disagreements on certainty ratings by discussion, provided justification for decisions to downgrade the ratings using footnotes in the table, and provided comments to aid readers' understanding of the review, when necessary. We used plain language statements to report these findings in the review (EPOC 2017c).

We summarised the findings in Summary of findings 1, and included the following outcomes.

- Quality of life (self-reported or parent proxy-report)
- Caregiver health, functioning, and quality of life
- Abuse of any type
- Hospitalisation rates
- Rates of emergency department attendance
- Resource use
- Days of school, college, daycare missed

If, during the review process, we became aware of an important outcome that we failed to list in our planned summary of findings table, we planned to include the relevant outcome in lieu of the outcome 'days of school, college, daycare missed' and explained the reasons for this in the section 'Differences between protocol and review'.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

We considered whether there was any additional outcome information that could not be incorporated into meta-analyses and noted this in the comments and stated if it supported or contradicted the information from the meta-analyses. If it was not possible to meta-analyse the data, we summarised the results in the text.

RESULTS

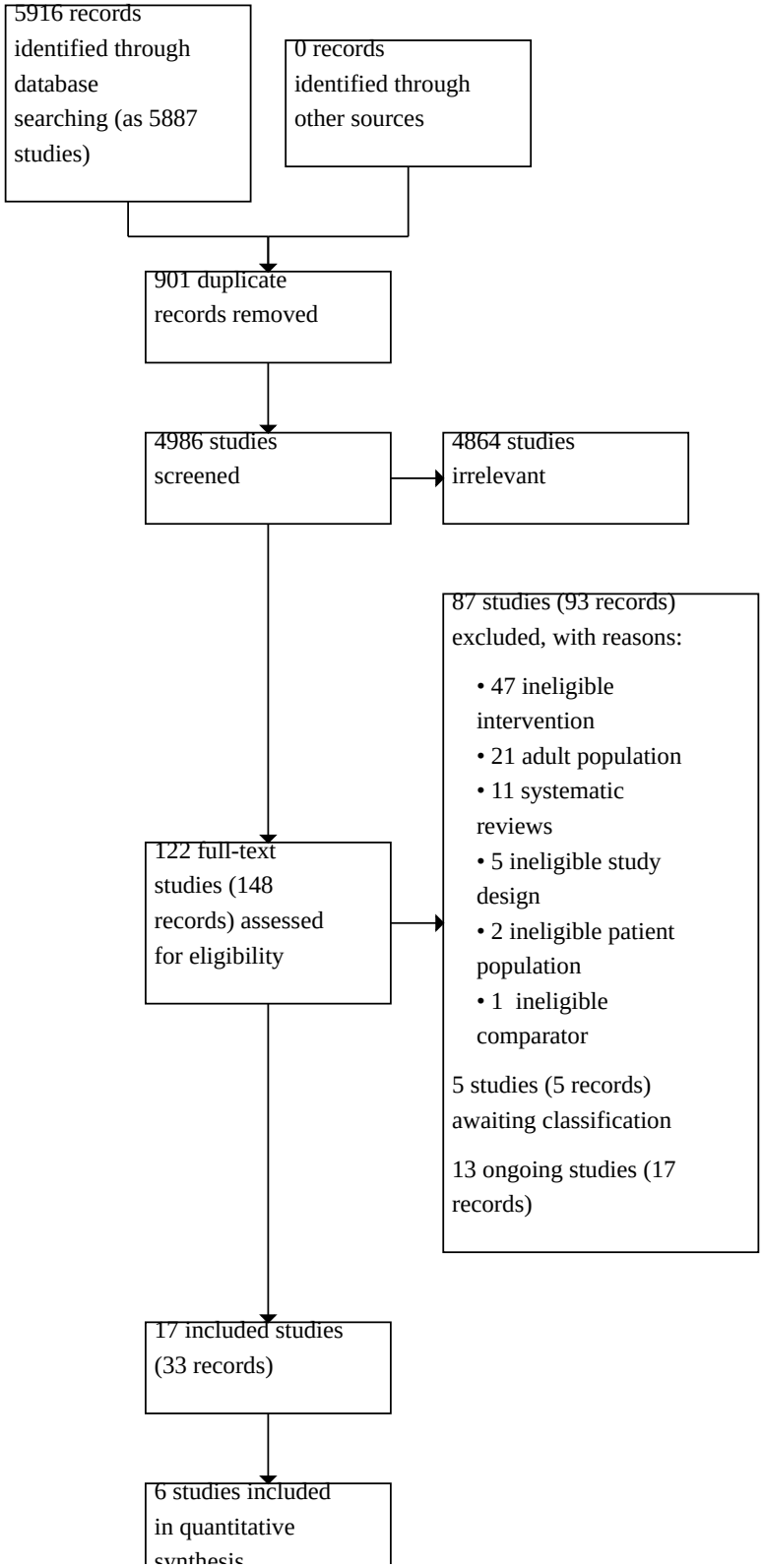
Description of studies

Results of the search

We identified 5916 records, 901 of which were excluded as duplicates. After title and abstract screening, we excluded a further 4864 records as irrelevant. Subsequently, we assessed 122 full-text records for eligibility. We included 17 studies (33 records) in the review, and excluded 87 studies (93 records). Five studies (5 records) are awaiting classification pending the release of more data. We identified 13 ongoing studies (17 records), which will be assessed in a future update of this review. See PRISMA flow diagram (Figure 1).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Figure 1. PRISMA flow diagram.



Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Figure 1. (Continued)

in quantitative synthesis (meta-analysis)

Included studies

The review includes 17 studies (2895 randomised participants) (Flores 2009; Frakking 2022; Frantatoni 2022; Gorelick 2006; Howe 2005; Karnick 2007; Katz 2014; Laffel 1998; Looman 2015; Parikh 2021; Seid 2010; Smaldone 2018; Spaic 2019; Svoren 2003; Weinstein 2021; White 2017; Ye 2013). See Characteristics of included studies table.

Sample sizes ranged from 28 (Smaldone 2018) to 445 participants (Ye 2013). Participants varied in age from ex-preterm infants up to adolescents (up to and including 18 years) transitioning to adult services. Studies generally took place in primary care or hospital outpatient settings in North America (other than White 2017 and Frakking 2022, which were conducted in Australia) with interventions ranging from a minimum of six months (Smaldone 2018) up to 30 months (Looman 2015). Six studies were primarily conducted in minority population groups (African American or Hispanic heritage) (Flores 2009; Gorelick 2006; Karnick 2007; Parikh 2021; Seid 2010; Smaldone 2018). Seven studies had two patient navigator intervention arms (with one of these arms solely patient navigation and the other patient navigation with the addition of education, psychological support, or video conferencing options, rather than telephone calls or text messaging) plus standard care arms (Gorelick 2006; Howe 2005; Karnick 2007; Katz 2014; Looman 2015; Seid 2010; Svoren 2003). Where these studies have been included for meta-analysis purposes, we combine patient navigator arms (see Data synthesis). Three studies did not report study outcomes pertinent to this review, but were included for risk of bias analysis (Howe 2005; Parikh 2021; White 2017).

Population

There was a broad range of chronic disease populations studied.

- Six studies in children and adolescents with type 1 diabetes mellitus (Howe 2005; Katz 2014; Laffel 1998; Spaic 2019; Svoren 2003; White 2017)
- Six studies in children and adolescents with asthma (Flores 2009; Gorelick 2006; Karnick 2007; Parikh 2021; Seid 2010; Weinstein 2021)
- Two studies in children and adolescents with complex care (Looman 2015; Ye 2013)
- One study in children and adolescents with sickle cell disease (Smaldone 2018)
- One study in ex-premature infants (Frantatoni 2022)
- One study in children with non-complex chronic disease (Frakking 2022)

Interventions and comparators

The Characteristics of included studies table and Table 1 summarise the characteristics of patient navigator interventions for the included studies.

Interventions

Patient navigators and their training

A variety of individuals fulfilled the patient navigator role including nurses (Gorelick 2006; Howe 2005; Karnick 2007; Looman 2015; Spaic 2019), allied health workers (Frakking 2022; Gorelick 2006; Parikh 2021; Seid 2010; Spaic 2019), college educated but non-health professionals (Katz 2014; Laffel 1998; Svoren 2003), and lay people (Flores 2009; Frantatoni 2022). Three studies did not provide specific information regarding the patient navigator's previous education level (Smaldone 2018; Weinstein 2021; Ye 2013).

There was a wide variation in the training provided for the patient navigators. In seven studies, there was no formal training or it was not specifically mentioned (Frakking 2022; Gorelick 2006; Howe 2005; Karnick 2007; Parikh 2021; Spaic 2019; White 2017). At the opposite end of the spectrum, four studies provided an intensive research protocol or disease-specific training with written or in-person training (or combinations of these) (Flores 2009; Frantatoni 2022; Smaldone 2018; Weinstein 2021).

Activities or assistance provided (e.g. focus of intervention)

All study patient navigators had care co-ordination as the main component of their intervention. Furthermore, most patient navigators also focused on health literacy with the exception of Looman 2015, Laffel 1998, White 2017, and Ye 2013. Symptom reduction was a focus for nine studies (Flores 2009; Frantatoni 2022; Howe 2005; Karnick 2007; Katz 2014; Parikh 2021; Smaldone 2018; Spaic 2019; Weinstein 2021). Financial or social assistance (or both) was a feature of six studies (Flores 2009; Frantatoni 2022; Laffel 1998; Seid 2010; Svoren 2003; Weinstein 2021). Transition care was a focus for two studies (Spaic 2019; White 2017). For a detailed description of each patient navigator's role, refer to Table 1.

Duration of patient navigator intervention

There was a wide variation in the duration of patient navigator intervention between studies. The shortest duration was five to six weeks (Seid 2010), and the longest was up to 24 months (Katz 2014; Looman 2015; Svoren 2003; White 2017; Ye 2013). There was limited information on the amount of time each patient navigator spent with children/adolescents and their families during each intervention. This ranged from a text message (e.g. a reminder text about an upcoming appointment) (Smaldone 2018; Spaic 2019; White 2017), to an in-person visit of one hour or more (Weinstein 2021). Even within studies, the contact between patient navigator and their children/adolescents could vary over time (Flores 2009;

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frantatoni 2022; Howe 2005; Parikh 2021; Smaldone 2018; Spaic 2019; Weinstein 2021).

Frequency and type of patient navigator intervention

Both the frequency and type of patient navigator intervention differed greatly in each study. Modality of interventions included text messaging, telephone calls, emails, video/conference calls, and in-person reviews. This ranged from daily text messages (Smaldone 2018) to quarterly in-person reviews (Svoren 2003). Six studies did not explicitly report the frequency of intervention (Frakking 2022; Karnick 2007; Laffel 1998; Looman 2015; White 2017; Ye 2013).

Comparator

All studies used standard care as the comparator.

Location of intervention

Six studies conducted patient navigator interventions during a scheduled outpatient or general practitioner clinic visit (Frakking 2022; Katz 2014; Looman 2015; Smaldone 2018; Spaic 2019; Ye 2013). Four studies conducted patient navigator interventions at the child/adolescent's home (Flores 2009; Gorelick 2006; Smaldone 2018; Weinstein 2021). Other settings included community centres or church (Flores 2009), neonatal intensive care unit (Frantatoni 2022), coffee shop (Smaldone 2018), schools or the homes of family/friends (Weinstein 2021).

Outcomes

Primary outcomes

Quality of life data were reported in two components – **child/adolescent reported** and **parent-proxy reported**. There was a wide variety of tools used to measure quality of life outcomes – some generic and some disease specific, implemented at varying time points either during or after the intervention period.

Nine studies reported **self-reported quality of life** (child/adolescent) (Flores 2009; Frakking 2022; Katz 2014; Looman 2015; Seid 2010; Smaldone 2018; Spaic 2019; Weinstein 2021; Ye 2013), and four studies reported parent proxy report of child quality of life outcomes (Katz 2014; Seid 2010; Smaldone 2018; Weinstein 2021). Assessment was using the following: Paediatric Quality of Life Inventory (Flores 2009; Frakking 2022; Katz 2014; Looman 2015; Seid 2010; Smaldone 2018; Ye 2013), Diabetes Quality of Life score (DQL using the 'general' health score component) (Spaic 2019), and the Children's Depression Inventory 2 (Weinstein 2021).

Six studies reported **parent/carer quality of life** outcomes (Flores 2009; Frakking 2022; Gorelick 2006; Looman 2015; Weinstein 2021; Ye 2013). There was variety in the tools used (generic versus disease specific) and at what point during the intervention carer quality of life outcomes were assessed. The studies used different quality of life measuring tool: Paediatric Carer Quality of Life (Flores 2009), Paediatric Quality of Life Family Impact Module (Frakking 2022), Median Integrated Therapeutics Group Child Asthma Short form (median score, Gorelick 2006), Parent Kessler Distress score (measuring anxiety and depression, Ye 2013), Family Impact Model (Looman 2015), and the Patient Health Questionnaire (Weinstein 2021).

No study reported data on **abuse of any type** against the young person, siblings, family, or the patient navigator themselves.

Secondary outcomes

- Hospital admissions: eight studies (Flores 2009; Frantatoni 2022; Gorelick 2006; Karnick 2007; Looman 2015; Seid 2010; Svoren 2003; Weinstein 2021)
- Emergency/unplanned presentations: eight studies (Flores 2009; Frantatoni 2022; Gorelick 2006; Karnick 2007; Looman 2015; Seid 2010; Svoren 2003; Weinstein 2021)
- Resource use: four studies (Flores 2009; Frakking 2022; Karnick 2007; Weinstein 2021)
- Days of school/college/daycare missed: two studies (Flores 2009; Frakking 2022)

There was variation between studies in terms of the activities, procedures, training of patient navigators, activities provided by the patient navigators, target populations and whether the needs of participants were considered, mode of intervention delivery, frequency and duration, and details on the adherence and fidelity of the intervention (if assessed). For these reasons, we were unable to meta-analyse all studies for each reported outcome. See the Discussion for more details on this and refer to Table 1 for a full review of each study's patient navigator intervention.

Attempts to obtain further information

We attempted to contact the following authors for more information.

Lemke 2018: we attempted to contact the corresponding author to determine if we could extract data for people aged less than 19 years only as this was a mixed cohort of children and adults. However, the corresponding author is no longer working with this research group and did not respond.

Looman 2015: we contacted the corresponding author to request raw data for emergency department presentations and hospitalisations. This was kindly provided and used in our analyses.

Spaic 2019: we attempted to contact the first author of this paper to obtain raw data for emergency department presentations and hospitalisations; however, there was no response.

White 2017: a type 1 diabetes mellitus study. We contacted the first author of this paper to request the proportion of people aged less than 19 years at enrolment and information about a parallel psychosocial study which may have contained some outcome measures of interest to us. She confirmed that more than 50% of participants were aged less than 19 years at enrolment but that study outcomes were not relevant to our review. White 2017 was included for the risk of bias analysis.

Excluded studies

We excluded 87 studies from this review. See Characteristics of excluded studies table.

Forty-seven studies had an ineligible intervention (ACTRN12622000478718; Aish 2017; Barrera 2020; Campbell 2015; Chen 2022; Chernoff 2002; Fernandez-Ruiz 2021; Grady 2019; ISRCTN13535901; Jackson 2007; Jonas 2022; Kaslow 2000; Krieger 2002; Leung 2020; Mackie 2014; Mackie 2018; MacKie 2019; Morisaki-Nakamura 2022; Nansel 2009; NCT01511341; NCT01521247; NCT01587105; NCT02141893; NCT02277327; NCT02331082; NCT02877823; NCT03028233; NCT03066596;

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT03106727; NCT03196024; NCT03317977; NCT03800459; NCT03989986; NCT03995953; NCT04115813; NCT04414553; NCT05292365; Overbury 2021; Parker 2008; Robertson 1998; Saarijarvi 2022; Steinbeck 2012; Sullivan-Bolyai 2010; Takaro 2004; Thomsen 2022; Tschank 2018; Yun 2015).

Twenty-one studies enroled an adult population (Geldsetzer 2017; Lemke 2018; NCT01659294; NCT01792661; NCT01900470; NCT02114515; NCT02197845; NCT02944136; NCT02960542; NCT03092063; NCT03176576; NCT03178773; NCT03699748; NCT04388592; NCT04761016; NCT04790604; NCT04790617; NCT04791267; NCT05455216; Pape 2022; Plant 2015).

Specifically, Pape 2022 and Plant 2015 were excluded as most participants in these cohorts were aged over 19 years. We contacted the authors of Lemke 2018 to see if they were able to provide data for participants aged under 19 years; however, there was no response from the authors and thus this paper was excluded.

Eleven were excluded (after their reference lists had been reviewed) due to being systematic reviews (Chu 2015; Coombes 2018; Flynn 2022; Garcia-Rodriguez 2022; Golfenshtein 2016; Le Roux 2017; Lewin 2005; Mardhiyah 2022; McBrien 2018; Raphael 2013; Yang 2022).

Five studies had an ineligible study design (e.g. not randomised controlled trials) (Arora 2015; Perry 2000; Saarijarvi 2021; Sequeira 2015; Sparring 2018).

Two studies enroled an ineligible patient population (Goff 2013; NCT03077425).

One study had an ineligible comparator (Berg 2022).

Studies awaiting classification

Five studies are awaiting classification pending further data being available (Characteristics of studies awaiting classification table)

- ACTRN12622001459718: Equity Pathways in Integrated Care in Cerebral Palsy (EPIC-CP): a pilot clinical trial of social prescribing for children and young people with cerebral palsy and their parents/caregivers
- Goyal 2022: a multicentre paediatric to adult care transition intervention programme to improve clinic visit adherence and clinical outcomes among adolescents and emerging adults with type 1 diabetes mellitus: protocol for a randomised controlled trial
- NCT05353998: efficacy of clinical decision support and sleep navigation (sleep pass)
- NCT05639088: improving transition care for adolescents and young adults with type 1 diabetes (SHIFT2 trial)
- Willems 2021: evaluation of a case management to support families with children diagnosed with spinal muscular atrophy – protocol of a controlled mixed-methods study

Ongoing studies

Thirteen studies remain ongoing (see Characteristics of ongoing studies table).

- Bollegala 2022: multimodal intervention to improve the transition of people with inflammatory bowel disease from paediatric to adult care: protocol for a randomised controlled trial
- Bryant-Stephens 2021: the West Philadelphia asthma care implementation study
- Jimenez 2021: feasibility and acceptability of a telephone-based intervention for Hispanic children to promote treatment adherence after traumatic brain injury: a pilot study
- Lipman 2019: integrating community health workers into the care of children with type 1 diabetes
- NCT01834456: comprehensive care of children with medical complexity
- NCT03648710: community health workers and mhealth for sickle cell disease care
- NCT04238949: community health workers in paediatric patients with newly diagnosed type 1 diabetes
- NCT05294042: patient navigators for children's community mental health services in high poverty urban communities
- Orkin 2019: complex care for kids Ontario
- Samuel 2019: evaluating innovations in transition from paediatric to adult care – the Transition Navigator Trial
- Smaldone 2019: HABIT efficacy and sustainability trial, a multicentre randomised controlled trial to improve hydroxyurea adherence in youth with sickle cell disease: a study protocol
- van Zwieten 2019: NAVK-KIDS trial: protocol for a multicentre, staggered randomised control trial of a patient navigator intervention in children with chronic kidney disease
- Wahi 2022: screening and addressing social needs of children and families enroled in a paediatric weight management programme: a protocol for a pilot randomised controlled trial

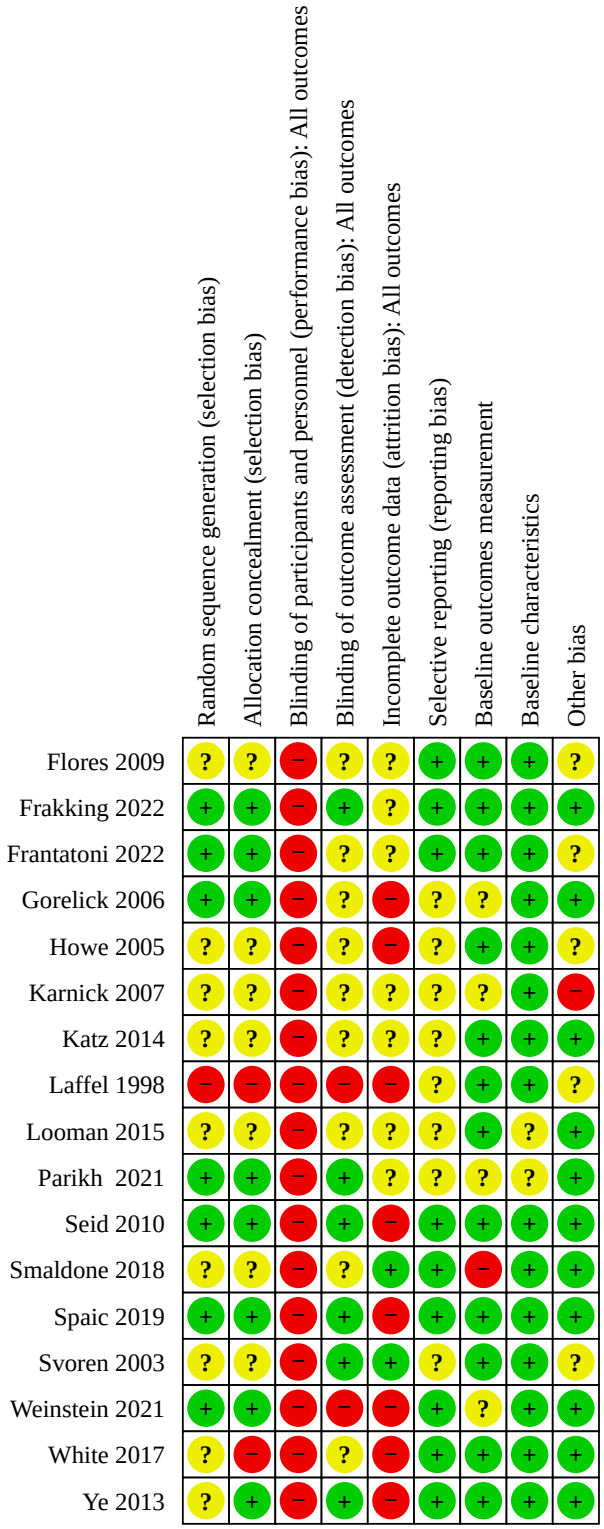
Risk of bias in included studies

See the risk of bias section in the Characteristics of included studies table for a detailed assessment of bias within each included study.

See Figure 2 and Figure 3 for a tabular and graphical summary of the assessment of bias within each included study.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Figure 2. (Continued)

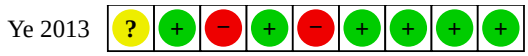
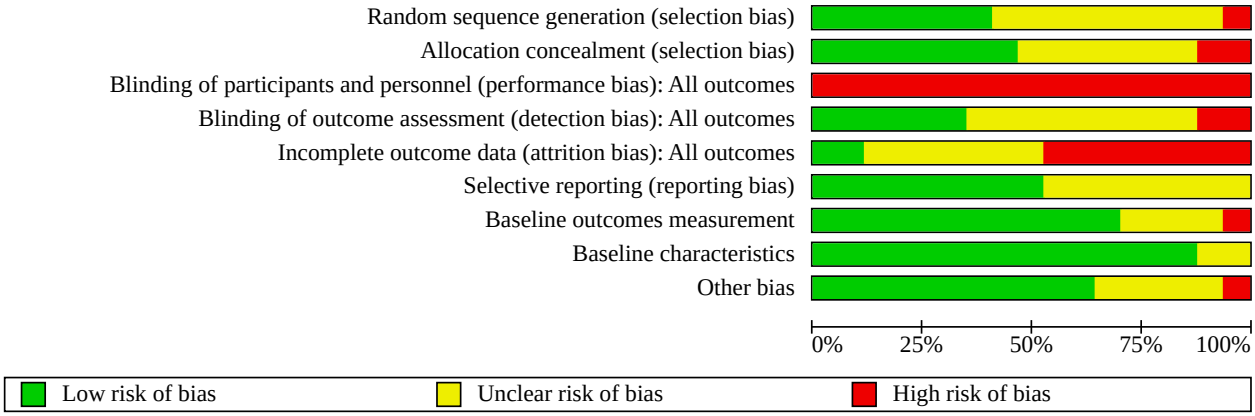


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Most studies were characterised by an unclear or high risk of bias across most domains. This was due to a lack of detail around randomisation procedures and allocation concealment, high levels of incomplete outcome data, and selective reporting. Using funnel plots to detect publication bias was not feasible due to the small number of studies.

Allocation

Random sequence generation

Nine studies were at unclear risk of bias (Flores 2009; Howe 2005; Karnick 2007; Katz 2014; Looman 2015; Smaldone 2018; Svoren 2003; White 2017; Ye 2013). These studies were reported to be a 'randomised' controlled trial or having 'randomly assigned participants' to treatment groups. However, the methods that were used to carry out the randomisation process were not described in sufficient detail. Laffel 1998 was at high risk of bias as there was no information around allocation procedures.

The remaining seven studies were at low risk of bias (Frakking 2022; Frantatoni 2022; Gorelick 2006; Parikh 2021; Seid 2010; Spaic 2019; Weinstein 2021). These studies described with adequate detail the methods that were used to carry out the randomisation process.

Allocation concealment

Nine studies were at either high (Laffel 1998; White 2017) or unclear risk of bias (Flores 2009; Howe 2005; Karnick 2007; Katz 2014; Looman 2015; Smaldone 2018; Svoren 2003) due to either a complete lack of information surrounding allocation concealment or very limited information about allocation. The remaining eight studies provided detailed information detailing the allocation concealment process and were at low risk of bias (Frakking 2022; Frantatoni 2022; Gorelick 2006; Parikh 2021; Seid 2010; Spaic 2019; Weinstein 2021; Ye 2013).

Blinding

Blinding of participants and personnel

Given the nature of the intervention, it was not possible to 'blind' participants to their allocated intervention. For this reason, all studies were at high risk of bias.

Blinding of outcome assessors

Six studies provided detailed explanations of a separate data collection and analysis team blinded to group allocation and were at low risk of bias (Frakking 2022; Parikh 2021; Seid 2010; Spaic 2019; Svoren 2003; Ye 2013). The remaining studies either provided no (high risk of bias; Laffel 1998; Weinstein 2021), or insufficient explanation (unclear risk of bias; Flores 2009; Frantatoni 2022; Gorelick 2006; Howe 2005; Karnick 2007; Katz 2014; Looman 2015; Smaldone 2018; White 2017), with respect to blinding of outcome assessors.

Incomplete outcome data

Fifteen studies were at either high (Gorelick 2006; Howe 2005; Laffel 1998; Seid 2010; Spaic 2019; Weinstein 2021; White 2017; Ye 2013), or unclear (Flores 2009; Frakking 2022; Frantatoni 2022; Karnick 2007; Katz 2014; Looman 2015; Parikh 2021), risk of bias due to high attrition rates (up to 41% of participants, Flores 2009), extrapolation of outcome data (nine months of outcome data extrapolated to reflect 12 months of data, Karnick 2007), or a failure to account for why participants/families were lost to follow-up. In one study, almost 50% of participants in the control arm never received a baseline clinic visit (Weinstein 2021). Two studies were at low risk due to relatively low attrition rates (up to 10.7%, Smaldone 2018), and all participants in these studies were accounted for from the start to the end of the study (Smaldone 2018; Svoren 2003).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Selective reporting

Eight studies did not provide trial registration numbers or details to an a priori-published protocol and were at unclear risk of bias (Gorelick 2006; Howe 2005; Karnick 2007; Katz 2014; Laffel 1998; Looman 2015; Parikh 2021; Svoren 2003). The remaining studies were at low risk of bias (Flores 2009; Frakking 2022; Frantatoni 2022; Seid 2010; Smaldone 2018; Spaic 2019; Weinstein 2021; White 2017; Ye 2013).

Other potential sources of bias

Baseline outcomes measurement

Twelve studies had equal outcomes measurements at baseline (Flores 2009; Frakking 2022; Frantatoni 2022; Howe 2005; Katz 2014; Laffel 1998; Looman 2015; Seid 2010; Spaic 2019; Svoren 2003; White 2017; Ye 2013). Smaldone 2018 had a high risk of bias due to differences between the percentage decrease in haemoglobin F from personal best between groups. The remaining studies were unclear for the following reasons; Gorelick 2006 had 55 (20%) participants missing baseline chronic severity categorisation, without further information; Karnick 2007 had a higher number of unscheduled clinic visits at baseline for the intervention group; Parikh 2021 had differences in asthma classification and asthma control between groups; Weinstein 2021 had less hospitalisation for asthma in the asthma education group compared to the community health worker group.

Baseline characteristics

Fifteen studies had equal baseline characteristics for both standard care and patient navigation groups (Flores 2009; Frakking 2022; Frantatoni 2022; Gorelick 2006; Howe 2005; Karnick 2007; Katz 2014; Laffel 1998; Seid 2010; Smaldone 2018; Spaic 2019; Svoren 2003; Weinstein 2021; White 2017; Ye 2013). However, Looman 2015 reported a difference in the level of parental education in the standard care group (e.g. more parents in this group had college level education; 57% in standard care group versus 29% in intervention group; P = 0.017). Parikh 2021 reported differences in the age of participants at baseline (6 years in intervention group versus 8.5 years in control group). There was no comment on how or whether these differences were accounted for in the statistical analysis.

Sources of funding and conflicts of interest

Five studies did not declare whether the authors had any conflict of interest (Frantatoni 2022; Howe 2005; Laffel 1998; Karnick 2007; Svoren 2003). Howe 2005 did not disclose how their research was funded. Of note, the 12-month outcome data of Karnick 2007 were extrapolated from nine months (the study was shortened due to funding issues). This is particularly relevant given the study was conducted on people with asthma (a seasonal condition) and almost certainly would have affected their outcomes. For the reasons outlined above, Karnick 2007 was deemed at high risk of bias. Five studies were at unclear risk of bias as they were missing at least one conflict of interest, ethics, or funding data (Flores 2009; Frantatoni 2022; Howe 2005; Laffel 1998; Svoren 2003). The remaining studies were at low risk of bias (Frakking 2022; Gorelick 2006; Katz 2014; Looman 2015; Parikh 2021; Seid 2010; Smaldone 2018; Spaic 2019; Weinstein 2021; White 2017; Ye 2013).

Effects of interventions

See: **Summary of findings 1** Patient navigators compared to standard care for children and adolescents with chronic diseases

See Summary of findings 1.

Given the heterogeneity and small number of participants in these studies, we were unable to undertake any of the subgroup analyses as described a priori in the protocol (Lalji 2021).

Quality of life

Child self-reported at 12 months of care

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on self-reported quality of life of children with chronic illness (SMD 0.63, 95% CI −0.20 to 1.47; I^2 = 96%; 4 studies, 671 participants; very low-certainty evidence; Analysis 1.1).

Parent proxy-reported at 12 months of care

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on parent proxy reported quality of life of children with chronic illness (SMD 0.09, 95% CI −2.21 to 2.40; I^2 = 99%; 2 studies, 309 participants; very low-certainty evidence; Analysis 1.2).

Caregiver health, functioning, and quality of life at 24 months of care

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on parents' or caregivers' quality of life (SMD −1.98, 95% CI −4.13 to 0.17; I^2 = 99%; 3 studies, 757 participants; very low-certainty evidence; Analysis 2.1).

Abuse of any type

No studies reported abuse of any type.

Hospitalisation rates

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on the number of hospital admissions (MD −0.05, 95% CI −0.34 to 0.23; I^2 = 99%; 2 studies, 381 participants; very low-certainty evidence; Analysis 3.1).

Rates of emergency department attendance

The evidence is very uncertain about the effects of patient navigator programmes compared with standard care on the number of presentations to the emergency department (MD 0.06, 95% CI −0.23 to 0.34; I^2 = 98%; 2 studies, 381 participants; very low-certainty evidence; Analysis 4.1).

Resource use

There may be health economic benefits to patient navigator interventions. Four studies (629 participants) reported data on resource use (Carter 2022; Flores 2009; Karnick 2007; Weinstein 2021). However, given the variation in units of analysis used, meta-analysis was not possible. Karnick 2007 reported a cost saving (in 2007) of 4503.44 United States dollars (USD) per participant over a 12-month intervention period for the patient navigator group compared with USD 4020.76 per participant in the standard care group. Weinstein 2021 reported that patient navigators were

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

more cost-effective than standard asthma care educators (USD 74 per session for patient navigators versus USD 135 per session for standard care). Flores 2009 reported the incremental cost-effectiveness ratio for the patient navigator intervention was USD 597.10 per asthma exacerbation-free day gained, indicating a total cost savings for patient navigator intervention participants. Overall, however, the general quality of the data was poor.

Carter 2022 (in a health economic assessment of Frakking 2022, published separately) reported the care co-ordination arm cost an average of 17 Australian dollars (AUS) per participant extra (based on 2021) in additional health system costs and gained an additional 0.031 quality-adjusted life year per participant (95% CI −0.29 to 0.092) over the 12-month intervention period. This is the most in-depth health economic evaluation of the costs of a patient navigator programme of all studies that reported on this outcome.

Days of school/daycare/college missed

One study (220 participants) reported an improvement in *both* control and intervention groups at 12 months of intervention compared with baseline (control: 1.9 days, 95% CI 1.2 to 3.5 before the study versus 0.80 days, 95% CI 0.4 to 1.2 at 12 months; P = 0.01; patient navigation: 2.2 days, 95% CI 1.5 to 3.0 before the study versus 1.0 days, 95% CI 0.6 to 1.4 at 12 months; P = 0.01) (Flores 2009). However, there was no difference in the number of missed days *between* groups. One study (81 participants) reported children in the care co-ordination group experienced fewer missed school days when compared to the standard care group (mean −15.98 days, 95% CI −47.92 to 3.92) during the 12-month intervention period (Frakking 2022). However, there were no baseline data collected for either group.

DISCUSSION

Summary of main results

This systematic review has shown that based on currently available data, the effects of using patient navigators for children and adolescents with chronic disease are very uncertain. In the 17 included studies (2895 participants), the results had a very high degree of heterogeneity, a high or unclear risk of bias, and suboptimal methodological design or reporting.

Overall completeness and applicability of evidence

This review highlights the severe lack of high-quality randomised controlled trials investigating whether patient navigators improve outcomes for children and adolescents with chronic diseases. We identified significant gaps in the evidence as outlined below.

Major issues around the completeness of the evidence included the following.

- Lack of reporting and variability around patient navigator training. This contributed to the heterogeneity of the results.
- Outcome measures varied greatly by scale, unit of analysis, and time point. For these reasons, we were limited in the number of studies included for meta-analyses. Even for outcomes where meta-analysis was undertaken, results showed high statistical heterogeneity with the I^2 statistic above 95%.
- The intensity and duration of patient navigator interventions were vastly different between studies, ranging from six months to 30 months. It is unclear whether the duration of the patient navigation intervention is likely to modify the effect of the result; hence, this precluded meta-analysis for most studies.
- No study reported abuse as an adverse outcome. This is a major issue given the close contact a patient navigator potentially has with patients and their families.
- We acknowledge that, given the nature of the therapeutic intervention (patient navigation), many of these programmes will be community based and thus without a research/academic focus. This inherently creates an element of research bias in our current findings.
- It may be worth considering whether to include non-randomised studies in future updates of this review.

Major issues around the applicability of the evidence included the following.

- Fifteen studies were conducted in North American health systems with six studies specifically conducted in minority populations (African American, Hispanic) (Flores 2009; Frantatoni 2022; Gorelick 2006; Howe 2005; Karnick 2007; Katz 2014; Laffel 1998; Looman 2015; Parikh 2021; Seid 2010; Smaldone 2018; Spaic 2019; Svoren 2003; Weinstein 2021; Ye 2013). The applicability of these results to other health systems and populations globally may be limited, though it should be noted that patient navigator interventions are currently being postulated as a plausible and practical strategy to help overcome health inequities worldwide.
- We acknowledge there is significant heterogeneity across the different studies, and we were unable to evaluate the specific factors (clinical or methodological issues) that may explain the observed differences between studies as there were insufficient data within each participant group to perform subgroup analysis or a meta-regression.
- The patient populations varied significantly in age (from ex-preterm babies through to young adults) and in chronic disease status ranging from generally well with intermittent acute asthma to children requiring a high burden of care due to their physical and developmental limitations. Due to the limited number of heterogeneous studies, it was not possible to undertake subgroup analyses on specific patient groups as planned. However, there may be more of a benefit for this intervention for specific patient subgroups or with specific diseases (e.g. people with complex needs, young adults transitioning to adult services who are trying to navigate an adult health system for the first time or people with newly diagnosed diabetes who require intensive glucose monitoring).
- We acknowledge that there may be inherent differences in the purposes of hospital- versus community-based patient navigator. However, the ultimate goal of all patient navigator interventions is to help patients and their families to navigate the complex health and social systems with the possibility of health education and organisation of appointments in both hospital or community settings (or both). Therefore, future updates of this review should consider evaluating the differences in outcomes between the subgroups.
- No study examined safety-related data related to a patient navigation intervention.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Quality of the evidence

The certainty of the existing evidence was limited by suboptimal methodological design, specifically a failure to specify methods of randomisation and allocation concealment (risk of bias). In addition, a considerable number of studies had a high risk of attrition bias. The lack of uniformity of patient navigation interventions across all studies with specific respect to the *duration* and *intensity* of patient navigation further reduced the strength of the review (indirectness). It is because of this variability that we limited meta-analysis of outcomes to those studies that had the *same duration* of patient navigator intervention and *outcome measures taken at the same time interval* (generally 12 or 24 months). Even with these limitations, there was considerable statistical heterogeneity as evidenced by the I^2 values for all meta-analyses, which were 96% or greater, and all CIs which crossed 0 (imprecision and inconsistency). This affects the extent to which generalisable conclusions can be formed.

The above limitations suggest that additional studies are likely to change our confidence in the effect estimates (Guyatt 2008). Future studies would be further enhanced by uniformity in methodology and standardised outcome measures (Algurén 2021).

Potential biases in the review process

This review was conducted as per the protocol following prespecified inclusion criteria and used comprehensive literature searches to find all relevant studies. Patient navigation is a complex intervention and information and details regarding the intervention and comparator were incomplete. Therefore, we were unable to categorise the intervention based on duration and components of the intervention. Whilst all patient navigators received training before commencement, most studies did not provide specific details of the types of training and how it was delivered. Whilst we attempted to review all potential harms (including abuse against the navigator, patients, or family members) the detection of adverse effects may have been limited by our current search in this review.

We also acknowledge that we did not capture the findings of process evaluations within the individual trials as key outcomes in our review. We acknowledge that sometimes, the qualitative findings from these evaluations may have indicated positive experiences which were not seen quantitatively. Inclusion of the results of qualitative studies on this topic was beyond the scope of this review.

Agreements and disagreements with other studies or reviews

One systematic review has been published on this topic (McBrien 2018). Of the 74 articles included in McBrien 2018, only two of these were conducted specifically in paediatric populations (Laffel 1998; Svoren 2003; both of these studies were included in our review) with the remaining studies conducted primarily in adults with cancer, diabetes, and HIV/AIDS, who have markedly different chronic care pathways and needs to children. Of note, McBrien 2018 reported that patient navigator programmes improved processes of care (in adults) but few of the 72 adult studies reported on patient experience, clinical outcomes, or health economic costs. These outcomes, to our mind, are the most relevant outcomes when considering the implementation of an intervention such as a patient navigator programme.

The use of patient navigators for children and adolescents is clearly an area of new research and interest. We have identified 13 ongoing studies and a further five studies are awaiting classification (refer to Characteristics of ongoing studies and Characteristics of studies awaiting classification tables), which we will assess in a future update of this review.

AUTHORS' CONCLUSIONS

Implications for practice

Based on currently available data, the effects of using patient navigators for children and adolescents with chronic diseases are unclear.

Implications for research

Further well-designed randomised controlled trials are needed to examine both patient- and carer-centred outcomes (such as quality of life data and function as measured by days of school/daycare missed or work days missed by parents) as well as health-related outcomes (such as number of emergency department presentations, unplanned hospital admissions, or attendance at outpatient appointments).

It is important for future randomised controlled trials to report adverse outcomes and events for the child, family unit, or patient navigator given that no study published to date has recorded this information. Given how closely patient navigators work with patients and families, it is important to ensure the safety of this role.

Individual chronic disease groups may also report specific disease markers of control such as glycated haemoglobin, lung function, or salbutamol use, which could then be used for future subgroup analysis of 'common' chronic conditions such as type 1 diabetes mellitus or asthma. Developmental delay or cognitive impairment (or both) could also be a potential effect modifier of this intervention and should be considered for subgroup analysis in future updates of this topic.

Finally, the health economic/resource use aspect of patient navigator interventions needs to be reported as these will differ greatly depending on the population group, duration of intervention, and the health system or country in which the navigator is working.

ACKNOWLEDGEMENTS

Editorial and peer-reviewer contributions

The following people conducted the editorial process for this article.

- Sign-off Editor (final editorial decision): Michelle Hilton-Boone
- Managing Editor (selected peer reviewers, collated peer-reviewer comments, provided editorial guidance to authors, edited the article): Sam Hinsley, Cochrane Central Editorial Service
- Editorial Assistant (conducted editorial policy checks and supported editorial team): Lisa Wydrzynski, Cochrane Central Editorial Service

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

- Copy Editor (copy editing and production): Anne Lawson, Cochrane Central Production Service
- Peer-reviewers (provided comments and recommended an editorial decision): Brynn Fowler, Northwestern University, Chicago, Illinois, USA (content review); Shazeen Suleman, Stanford University, Stanford, California, USA (content review); Jennifer Hilgart, Cochrane (methods review); Ina Monsef Cochrane Haematology, Department I of Internal Medicine, Center for Integrated Oncology Aachen Bonn Cologne Duesseldorf, Faculty of Medicine and University Hospital Cologne, University of Cologne, Germany (search review). Two additional peer reviewers provided content peer review but chose not to be publicly acknowledged.

National Institute for Health Research (NIHR), via Cochrane Infrastructure funding to the Effective Practice and Organisation of Care (EPOC) Group. The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, National Health Service (NHS), or the Department of Health.

The Australasian Satellite of the Cochrane EPOC Group is funded by Cochrane, and receives infrastructure support from Monash University, Monash Department of Clinical Epidemiology – Cabrini.

The authors would like to thank their local Information Specialists Nicole Rayner and Anh Kieu who both assisted with the search update and Information Specialist Narelle Willis for sharing her insider knowledge of Review Manager and GRADEpro GDT software (GRADEpro GDT; RevMan 2024).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

REFERENCES

References to studies included in this review

Flores 2009 *{published data only}*

* Flores G, Bridon C, Torres S, Perez R, Walter T, Brotanek J, et al. Improving asthma outcomes in minority children: a randomized, controlled trial of parent mentors. *Pediatrics* 2009;**124**(6):1522-32. [DOI: 10.1542/peds.2009-0230]

Moorman JE, Rudd RA, Johnson CA, King M, Minor P, Bailey C, et al, Centers for Disease Control and Prevention (CDC). National surveillance for asthma: United States, 1980–2004. *MMWR Surveillance Summary* 2007;**56**(8):1-54.

Frakking 2022 *{published data only}***10.1001/jamapediatrics.2021.5465**

ACTRN12617001188325. A randomised controlled study to evaluate an the effect of an intergrated care pathway on quality of life for children with chronic disease – connecting the dots in healthcare provision. www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12617001188325 (first received 8 August 2017). [ANZCTR.ORG.AU: ACTRN12617001188325]

Carter HE, Waugh J, Chang AB, Shelton D, David M, Weir KA, et al. Cost-effectiveness of care coordination for children with chronic noncomplex medical conditions: results from a multicentre randomized clinical trial. *Value Health* 2022;**25**(11):1837-45. [DOI: 10.1016/j.jval.2022.06.008]

Frakking T, Hsien-Jin T, Shelton D, Moloney S, Ward D, Annetts K, et al. Effect of care coordination using an allied health liaison officer for chronic noncomplex medical conditions in children: a multicenter randomized clinical trial. *JAMA Pediatrics* 2022;**176**(3):244-52. [DOI: 10.1001/jamapediatrics.2021.5465]

Frantatoni 2022 *{published data only}*

Carty CL, Soghier LM, Kritikos KI, Tuchman LK, Jiggetts M, Glass P, et al. The Giving Parents Support Study: a randomized clinical trial of a parent navigator intervention to improve outcomes after neonatal intensive care unit discharge. *Contemporary Clinical Trials* 2018;**70**:117-34. [DOI: 10.1016/j.cct.2018.05.004]

Frantatoni K, Soghier L, Kritikos K, Jacangelo J, Herrera N, Tuchman L, et al. Giving parents support: a randomized trial of peer support for parents after NICU discharge. *Journal of Perinatology* 2022;**42**:730-7. [DOI: 10.1038/s41372-022-01341-5]

Gorelick 2006 *{published data only}***10.1542/peds.2005-2000J**

* Gorelick MH, Meurer JR, Walsh-Kelly CM, Brousseau DC, Grabowski L, Cohn J, et al. Emergency department allies: a controlled trial of two emergency department-based follow-up interventions to improve asthma outcomes in children. *Pediatrics* 2006;**117**(4 Suppl 2):S127-34. [DOI: 10.1542/peds.2005-2000J]

Howe 2005 *{published data only}*

Howe CJ, Jawad AF, Tuttle AK, Moser JT, Preis C, Buzby M, et al. Education and telephone case management for children with type 1 diabetes: a randomized controlled trial. *Journal of Pediatric Nursing* 2005;**20**(2):83-95. [DOI: 10.1016/j.pedn.2004.12.010]

Karnick 2007 *{published data only}***10.1080/02770900601125391**

* Karnick P, Margellos-Anast H, Seals G, Whitman S, Aljadeff G, Johnson D. The pediatric asthma intervention: a comprehensive cost-effective approach to asthma management in a disadvantaged inner- city community. *Journal of Asthma* 2007;**44**(1):39-44. [DOI: 10.1080/02770900601125391]

Katz 2014 *{published data only}***10.1111/pedi.12065**

Katz ML, Volkening LK, Anderson BJ, Laffel LM. Family-based psychoeducation and care ambassador intervention to improve glycemic control in youth with type 1 diabetes: a randomized trial. *Pediatric Diabetes* 2014;**15**:142-50. [DOI: 10.1111/pedi.12065]

Laffel 1998 *{published data only}*

Laffel LM, Brackett J, Ho J, Anderson BJ. Changing the process of diabetes care improves metabolic outcomes and reduce hospitalisations. *Quality Management in Health Care* 1998;**6**(4):53-62.

Looman 2015 *{published data only}*

* Looman WS, Antolick M, Cady RG, Lunos SA, Garwick AE, Finkelstein SM. Effects of a telehealth care coordination intervention on perceptions of health care by caregivers of children with medical complexity: a randomized controlled trial. *Journal of Pediatric Health Care* 2015;**29**(4):352-63. [DOI: 10.1016/j.pedhc.2015.01.007]

Looman WS, Hullsiek RL, Pryor L, Mathiason MA, Finkelstein SM. Health-related quality of life outcomes of a telehealth care coordination intervention for children with medical complexity: a randomized controlled trial. *Journal of Pediatric Health Care* 2018;**32**(1):63-75. [DOI: 10.1016/j.pedhc.2017.07.007]

McKissick HD, Cady RG, Looman WS, Finkelstein SM. The impact of telehealth and care coordination on the number and type of clinical visits for children with medical complexity. *Journal of Pediatric Health Care* 2017;**31**(4):452-8. [DOI: 10.1016/j.pedhc.2016.11.006]

Parikh 2021 *{published data only}***10.1080/02770903.2020.1795877**

* Parikh K, Richmond M, Lee M, Fu L, McCarter R, Hinds P, et al. Outcomes from a pilot patient-centered hospital-to-home transition program for children hospitalized with asthma. *Journal of Asthma* 2021;**58**(10):1384-94. [DOI: 10.1080/02770903.2020.1795877]

Seid 2010 *{published data only}***10.1093/jpepsy/jsp133**

Seid M, Varni JW, Gidwani P, Gelhard LR, Slymen DJ. Problem-solving skills training for vulnerable families of children with persistent asthma: report of a randomized trial on health-related quality of life outcomes. *Journal of Pediatric Psychology* 2010;**35**(10):1133-43. [DOI: 10.1093/jpepsy/jsp133]

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Smaldone 2018 *{published data only}*

Green NS, Manwani D, Matos S, Hicks A, Soto L, Castillo Y, et al. Randomized feasibility trial to improve hydroxyurea adherence in youth ages 10–18 years though community health workers: the HABIT study. *Pediatric Blood & Cancer* 2017;**64**:e26689. [DOI: 10.1002/pbc.26689]

Green NS, Manwani D, Soto L, Castillo Y, Ireland K, Jin Z, et al. A pilot intervention to improve hydroxyurea adherence in youth with sickle cell disease through community health workers: the "Habit" study. *Blood* 2016;**128**(22):1310. [DOI: 10.1182/blood.V128.22.1310.1310]

* Smaldone A, Findley S, Manwani D, Jia H, Green NS. HABIT, a randomized feasibility trial to increase hydroxyurea adherence, suggests improved health-related quality of life in youths with sickle cell disease. *Journal of Pediatrics* 2018;**197**:177-185.e2. [DOI: 10.1016/j.jpeds.2018.01.054]

Smaldone A, Findley SE, Manwani D, JIa H, Green NS. HABIT, a feasibility trial to improve hydroxyurea adherence, improves quality of life in youth with sickle cell disease. *Blood* 2017;**130**(Suppl 1):869. [DOI: 10.1182/blood.V130.Suppl_1.869.869]

Spaic 2019 *{published data only (unpublished sought but not used)}***10.2337/dc18-2187**

Spaic T, Goldbloom E, Gallego P, Hramiak I, Lawson M, Malcolm J, et al. A structured transition program in young adults with type 1 diabetes is associated with improved satisfaction with diabetes care. *Diabetes* 2017;**66**:A77.

Spaic T, Mahon JL, Hramiak I, Byers N, Evans K, Robinson T, et al, on behalf of the Canadian Clinical Trial CCTN Study. Multicentre randomized controlled trial of structured transition on diabetes care management compared to standard diabetes care in adolescents and young adults with type 1 diabetes (Transition Trial). *BMC Pediatrics* 2013;**13**:163. [DOI: 10.1186/1471-2431-13-163]

* Spaic T, Robinson R, Goldbloom R, Gallego P, Hramiak I, Lawson ML, et al, for the JDRF Canadian Clinical Trial CCTN1102 Study Group. Closing the gap: results of the multicenter Canadian randomized controlled trial of structured transition in young adults with type 1 diabetes. *Diabetes Care* 2019;**42**:1018-26. [DOI: 10.2337dc18-2187]

Svoren 2003 *{published data only}***10.1542/peds.112.4.914**

* Svoren BM, Butler D, Levine BS, Anderson BJ, Laffel LM. Reducing acute adverse outcomes in youths with type 1 diabetes: a randomized, controlled trial. *Pediatrics* 2003;**112**(4):914-22. [DOI: 10.1542/peds.112.4.914]

Weinstein 2021 *{published data only}*

Martin M, Pugach O, Mosnaim G, Weinstein S, Rosales G, Roy A, et al. Community health worker asthma interventions for children: results from a clinically integrated randomized comparative effectiveness trial (2016–2019). *American Journal of Public Health* 2021;**111**(7):1328-37. [DOI: 10.2105/AJPH.2021.306272]

Martin MA, Pugach O, Mosnaim G, Weinstein S, Rosales G, Roy A, et al. Community health worker asthma interventions for children: results from a clinically integrated randomized comparative effectiveness trial (2016–2019). *American Journal of Public Health* 2021;**-**:e1-e10.

Martin MA, Pugach O, Rosales G, Songthangtham N, Weinstein S, Roy A, et al. Results from a randomized controlled trial comparing integrated asthma community health worker intervention to certified asthma educator services. *American Journal of Respiratory and Critical Care Medicine* 2020;**201**:1.

Mosnaim GS, Weinstein SM, Pugach O, Rosales G, Roy A, Walton S, et al. Design and baseline characteristics of a low-income urban cohort of children with asthma: the Asthma Action at Erie Trial. *Contemporary Clinical Trials* 2019;**79**:55-65. [DOI: 10.1016/j.cct.2019.02.006]

Pappalardo AA, Mosnaim G, Pugach O, Rosales G, Martin MA. Medication and environmental trigger changes in children receiving community asthma intervention: results from a randomized controlled trial. *American Journal of Respiratory and Critical Care Medicine* 2021;**203**:A1029. [DOI: 10.1164/ajrccm-conference.2021.203.1_MeetingAbstracts.A1029]

Weinstein SM, Pugach O, Rosales G, Mosnaim GS, Orozco K, Pappalardo AA, et al. Psychosocial moderators and outcomes of a randomized effectiveness trial for child asthma. *Journal of Pediatric Psychology* 2021;**46**(6):673-87. [DOI: 10.1093/jpepsy/jsab011]

White 2017 *{published data only (unpublished sought but not used)}***10.1016/S2352-4642(17)30089-5**

White M, O'Connell MA, Cameron FJ. Clinic attendance and disengagement of young adults with type 1 diabetes after transition of care from paediatric to adult services (TrACeD): a randomised, open-label, controlled trial. *Lancet Child and Adolescent Health* 2017;**1**:274-83. [DOI: 10.1016/S2352-4642(17)30089-5]

Ye 2013 *{published data only}***10.2147/clep.s48870**

Ye C, Browne G, Beyene J, Thabane L. A sensitivity analysis of the Children's Treatment Network trial: a randomized controlled trial of integrated services versus usual care for children with special health care needs. *Clinical Epidemiology* 2013;**5**:373-85. [DOI: 10.2147/CLEP.S48870]

References to studies excluded from this review

ACTRN12622000478718 *{published data only}*

ACTRN12622000478718. Deadly Ears at Discharge: Aboriginal health practitioner-led ear and hearing assessment and discharge planning for Aboriginal children at risk of severe ear infection. trialsearch.who.int/Trial2.aspx?TrialID=ACTRN12622000478718 (first received 25 March 2022).

Aish 2017 *{published data only}*

Aish H, Trenholme A, Byrnes C, Lennon D. An integrated model of care for children at risk of developing chronic respiratory disease. *International Journal of Integrated Care* 2017;**17**:3.

Arora 2015 *{published data only}*

Arora R, Ahuja S, Gupta S, Bagai P. Patient navigation and tracking to reduce abandonment and ensure follow-up in

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

children with cancer (PANTRACC) in India: a pilot study. *Pediatric Blood and Cancer* 2015;**62**:S197.

Barrera 2020 *{published data only}*

* Barrera M, Alexander S, Atenafu EG, Chung J, Hancock K, Solomon A, et al. Psychosocial screening and mental health in pediatric cancer: a randomized controlled trial. *Health Psychology* 2020;**39**(5):381-90. [DOI: 10.1037/hea0000825]

Barrera M, Desjardins L, Hancock K, Prasad S, Alexander S, Shama W, et al. Effectiveness of mapping psychosocial screening to resources: a one-year pilot randomized control intervention study. *Pediatric Blood & Cancer* 2020;**67**(Suppl 4):902. [DOI: 10.1002/pbc.28742]

Barrera M, Desjardins L, Prasad S, Shama W, Alexander S, Szatmari P, et al. Pilot randomized psychosocial trial of a screening intervention in pediatric oncology. *Psycho-oncology* 2022;**31**:735-44. [DOI: 10.1002/pon.5857]

Desjardins L, Hancock K, Szatmari P, Alexander S, Shama W, De Souza C, et al. Protocol for mapping psychosocial screening to resources in pediatric oncology: a pilot randomised controlled trial. *Pilot and Feasibility Studies* 2021;**7**:143. [DOI: 10.1186/s40814-021-00878-0]

Berg 2022 *{published data only}*

Berg KL, Mihaila I, Feinstein RT, Shiu CS, Gussin H, Acharya K, et al. BEhavioral Health Stratified Treatment (B.E.S.T.) to optimize transition to adulthood for youth with intellectual and/or developmental disabilities. Contemporary Clinical Trials 2024;**136**:107374. [DOI: 10.1016/j.cct.2023.107374]

Campbell 2015 *{published data only}*

Campbell JD, Brooks M, Hosokawa P, Robinson J, Song L, Krieger J. Community health worker home visits for Medicaid-enrolled children with asthma: effects on asthma outcomes and costs. *American Journal of Public Health* 2015;**105**(11):2366-72.

Chen 2022 *{published data only}*

Chen HW, Limmer EE, Joseph AK, Kinser K, Trevino A, Valencia A, et al. Efficacy of a lay community health worker (promotoras de salud) program to improve adherence to emollients in Spanish-speaking Latin American pediatric patients in the United States with atopic dermatitis: a randomized, controlled, evaluator-blinded study. *Pediatric Dermatology* 2022;**40**(1):69-77.

Chernoff 2002 *{published data only}*

Chernoff RG, Ireys HT, DeVet KA, Kim YJ. A randomized, controlled trial of a community-based support program for families of children with chronic illness: pediatric outcomes. *Archives of Pediatrics & Adolescent Medicine* 2002;**156**(6):533-9.

Chu 2015 *{published data only}***https://dx.doi.org/10.1016/j.pedn.2015.05.022**

Chu PY, Maslow GR, von Isenburg M, Chung RJ. Systematic review of the impact of transition interventions for adolescents with chronic illness on transfer from pediatric to adult healthcare. *Journal of Pediatric Nursing* 2015;**30**(5):e19-27. [DOI: 10.1016/j.pedn.2015.05.022]

Coombes 2018 *{published data only}***https://dx.doi.org/10.1186/s12913-018-3263-y**

Coombes J, Hunter K, Mackean T, Holland AJ, Sullivan E, Ivers R. Factors that impact access to ongoing health care for First Nation children with a chronic condition. *BMC Health Services Research* 2018;**18**(1):448. [DOI: 10.1186/s12913-018-3263-y]

Fernandez-Ruiz 2021 *{published data only}*

Fernandez-Ruiz VE, Sole-Agusti M, Armero-Barranco D, Cauli O. Weight loss and improvement of metabolic alterations in overweight and obese children through the I2AO2 family program: a randomized controlled clinical trial. *Biological Research for Nursing* 2021;**23**(3):488-503.

Flynn 2022 *{published data only}*

Flynn AC, Suleiman F, Windsor-Aubrey H, Wolfe I, O'Keeffe M, Poston L, et al. Preventing and treating childhood overweight and obesity in children up to 5 years old: a systematic review by intervention setting. *Maternal & Child Nutrition* 2022;**18**(3):e13354.

Garcia-Rodriguez 2022 *{published data only}*

Garcia-Rodriguez F, Raygoza-Cortez K, Moreno-Hernandez L, Garcia-Perez R, Garza Lopez LE, Arana-Guajardo AC, et al. Outcomes of transitional care programs on adolescent chronic inflammatory systemic diseases: systematic review and meta-analyses. *Pediatric Rheumatology Online Journal* 2022;**20**(1):15.

Geldsetzer 2017 *{published data only}*

Geldsetzer P, Francis JM, Ulenga N, Sando D, Lema IA, Mboggo E, et al. The impact of community health worker-led home delivery of antiretroviral therapy on virological suppression: a non-inferiority cluster-randomized health systems trial in Dar es Salaam, Tanzania. *BMC Health Services Research* 2017;**17**(1):160.

Goff 2013 *{published data only}*

Goff SL, Pekow PS, White KO, Lagu T, Mazor KM, Lindenauer PK. IDEAS for a healthy baby – reducing disparities in use of publicly reported quality data: study protocol for a randomized controlled trial. *Trials* 2013;**14**:244.

Golfenshtein 2016 *{published data only}*

Golfenshtein N, Srulovici E, Deatrick JA. Interventions for reducing parenting stress in families with pediatric conditions: an integrative review. *Journal of Family Nursing* 2016;**22**(4):460-92.

Grady 2019 *{published data only}*

Grady KL, Andrei AC, Shankel T, Chinnock R, Miyamoto SD, Ambardekar AV, et al. Pediatric heart transplantation: transitioning to adult care (TRANSIT): feasibility of a pilot randomized controlled trial. *Journal of Cardiac Failure* 2019;**25**(12):948-58.

ISRCTN13535901 *{published data only}*

ISRCTN13535901. Lending an ear: "iPeer2Peer" plus "Teens Taking Charge" online self-management to empower children with arthritis. www.isrctn.com/ISRCTN13535901 (first received 4 February 2019).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Jackson 2007 *{published data only}*

* Jackson H. Case-managed telephone follow-up of diabetic children. ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB2007107632.xhtml (accessed 12 August 2024).

Jonas 2022 *{published data only}*

Jonas JA, Leu CS, Reznik M. A randomized controlled trial of a community health worker delivered home-based asthma intervention to improve pediatric asthma outcomes. *Journal of Asthma* 2022;**59**(2):395-406.

Kaslow 2000 *{published data only}*

Kaslow NJ, Collins MH, Rashid FL, Baskin ML, Griffith JR, Hollins L, et al. The efficacy of a pilot family psychoeducational intervention for pediatric sickle cell disease (SCD). *Families, Systems and Health* 2000;**18**(4):381-404.

Krieger 2002 *{published data only}*

Krieger J, Takaro TK, Song L, Beaudet N, Edwards K. A randomized controlled trial of asthma self-management support comparing clinic-based nurses and in-home community health workers: the Seattle-King County Healthy Homes II Project. *Archives of Pediatrics & Adolescent Medicine* 2009;**163**(2):141-9. [DOI: 10.1001/archpediatrics.2008.532]

Krieger JK, Takaro TK, Allen C, Song L, Weaver M, Chai S, et al. The Seattle-King County healthy homes project: implementation of a comprehensive approach to improving indoor environmental quality for low-income children with asthma. *Environmental Health Perspectives* 2002;**110 Suppl 2**:311-22.

Krieger JW, Takaro TK, Song L, Weaver M. The Seattle-King County Healthy Homes Project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers. *American Journal of Public Health* 2005;**95**(4):652-9.

Lemke 2018 *{published data only (unpublished sought but not used)}***10.1542/peds.2017-3168**

Lemke M, Kappel R, McCarter R, D'Angelo L, Tuchman LK. Perceptions of health care transition care coordination in patients with chronic illness. *Pediatrics* 2018;**141**(5):e2173168. [DOI: 10.1542/peds.2017-3168]

Le Roux 2017 *{published data only}***https://dx.doi.org/10.1136/bmjopen-2016-012338**

Le Roux E, Mellerio H, Guilmin-Crepon S, Gottot S, Jacquin P, Boulkedid R, et al. Methodology used in comparative studies assessing programmes of transition from paediatrics to adult care programmes: a systematic review. *BMJ Open* 2017;**7**(1):e102388. [DOI: 10.1136/bmjopen-2016-012338]

Leung 2020 *{published data only}*

Leung J, Al-Yahyawi N, Choi H, Stewart L, Tang T, Amed S. 28 – evaluation of a type 1 diabetes adolescent transition program. *Canadian Journal of Diabetes* 2020;**44**(7):S14.

Lewin 2005 *{published data only}*

Lewin SA, Dick J, Pond P, Zwarenstein M, Aja G, van Wyk B, et al. Lay health workers in primary and community health care. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No: CD004015. [DOI: 10.1002%2F14651858.CD004015.pub2]

Mackie 2014 *{published data only}*

Mackie AS, Islam S, Magill-Evans J, Rankin KN, Robert C, Schuh M, et al. Healthcare transition for youth with heart disease: a clinical trial. *Heart (British Cardiac Society)* 2014;**100**(14):1113-8.

Mackie 2018 *{published data only}*

Mackie AS, Rempel GR, Kovacs AH, Kaufman M, Rankin KN, Jelen A, et al. Transition intervention for adolescents with congenital heart disease. *Journal of the American College of Cardiology* 2018;**71**(16):1768-77.

MacKie 2019 *{published data only}*

MacKie AS, Rankin K, Yaskina M, Gingrich J, Schuh M, Williams E, et al. Randomized controlled trial of a transition intervention program for young adolescents with congenital heart disease. *Circulation* 2019;**140**:Abstract 12604.

Mardhiyah 2022 *{published data only}*

Mardhiyah A, Panduragan SL, Mediani HS. Reducing psychological impacts on children with chronic disease via family empowerment: a scoping review. *Healthcare* 2022;**10**(10):14.

McBrien 2018 *{published data only}***https://dx.doi.org/10.1371/journal.pone.0191980**

McBrien KA, Ivers N, Barnieh L, Bailey JJ, Lorenzetti DL, Nicholas D, et al. Patient navigators for people with chronic disease: a systematic review. *PLOS One* 2018;**13**(2):e0191980. [DOI: 10.1371/journal.pone.0191980]

Morisaki-Nakamura 2022 *{published data only}*

Morisaki-Nakamura M, Suzuki S, Kobayashi A, Kita S, Sato I, Iwasaki M, et al. Efficacy of a transitional support program among adolescent patients with childhood-onset chronic diseases: a randomized controlled trial. *Frontiers in Pediatrics* 2022;**10**:829602.

Nansel 2009 *{published data only}*

Nansel TR, Anderson BJ, Laffel LM, Simons-Morton BG, Weissberg-Benchell J, Wysocki T, et al. A multisite trial of a clinic-integrated intervention for promoting family management of pediatric type 1 diabetes: feasibility and design. *Pediatric Diabetes* 2009;**10**(2):105-15.

NCT01511341 *{published data only}*

NCT01511341. Impact of a telenursing service on satisfaction and health outcomes of children with inflammatory rheumatic diseases. clinicaltrials.gov/show/NCT01511341 (first received 12 January 2012).

NCT01521247 *{published data only}*

NCT01521247. Implementation of a pediatric-to-adult asthma transition program. clinicaltrials.gov/show/NCT01521247 (first received 23 January 2012).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT01587105 *{published data only}*

NCT01587105. Improving care for children with complex needs. clinicaltrials.gov/show/NCT01587105 (first received 25 April 2012).

NCT01659294 *{published data only}*

NCT01659294. Diabetes outcomes and nurse case manager study. clinicaltrials.gov/show/NCT01659294 (first received 12 August 2012).

NCT01792661 *{published data only}*

NCT01792661. Navigating the challenges of chronic kidney disease. clinicaltrials.gov/show/NCT01792661 (first received 12 February 2013).

NCT01900470 *{published data only}*

NCT01900470. Effectiveness of patient-centered community health worker support to help patients control chronic disease. clinicaltrials.gov/study/NCT01900470 (first received 11 July 2013).

NCT02114515 *{published data only}*

NCT02114515. Patient navigator to reduce readmissions. clinicaltrials.gov/study/NCT02114515 (first received 1 April 2014).

NCT02141893 *{published data only}*

NCT02141893. Effectiveness of a multi-level clinic and family asthma intervention with a randomized control trial. clinicaltrials.gov/show/NCT02141893 (first received 12 May 2014).

NCT02197845 *{published data only}*

NCT02197845. Enhancing use of hydroxyurea in sickle cell disease using patient navigators. clinicaltrials.gov/study/NCT02197845 (first received 21 July 2014).

NCT02277327 *{published data only}*

NCT02277327. Trial to reduce hospitalizations in children with medical complexity. clinicaltrials.gov/show/NCT02277327 (first received 24 October 2014).

NCT02331082 *{published data only}*

NCT02331082. Integrating pediatric care delivery in rural healthcare systems. clinicaltrials.gov/show/NCT02331082 (first received 8 August 2013).

NCT02877823 *{published data only}*

NCT02877823. Improving cardiometabolic health of youth on antipsychotic medication. clinicaltrials.gov/show/NCT02877823 (first received 7 June 2016).

NCT02944136 *{published data only}*

NCT02944136. Collaborative care intervention for cancer caregivers. clinicaltrials.gov/show/NCT02944136 (first received 18 October 2016).

NCT02960542 *{published data only}*

NCT02960542. HELP prevent cancer pilot study. clinicaltrials.gov/study/NCT02960542 (first received 31 October 2016).

NCT03028233 *{published data only}*

NCT03028233. Healthy kids & families: overcoming social, environmental and family barriers to childhood obesity prevention. clinicaltrials.gov/show/NCT03028233 (first received 10 January 2017).

NCT03066596 *{published data only}*

NCT03066596. Promoting asthma guidelines and management through technology-based intervention and care coordination. clinicaltrials.gov/show/NCT03066596 (first received 10 January 2017).

NCT03077425 *{published data only}*

NCT03077425. Obesity and caries in young south Asian children: a common risk factor approach. clinicaltrials.gov/show/NCT03077425 (first received 2 March 2017).

NCT03092063 *{published data only}*

NCT03092063. Using multifamily groups to improve self-management of type 2 diabetes. clinicaltrials.gov/show/NCT03092063 (first received 10 March 2017).

NCT03106727 *{published data only}*

NCT03106727. Evaluating the impact of a community health worker program in Neno, Malawi. clinicaltrials.gov/show/NCT03106727 (first received 3 April 2017).

NCT03176576 *{published data only}*

NCT03176576. Patient navigation in the adolescent and young adult (AYA) cancer population. clinicaltrials.gov/show/NCT03176576 (first received 2 June 2017).

NCT03178773 *{published data only}*

NCT03178773. Text-MED + FANS full trial. clinicaltrials.gov/show/NCT03178773 (first received 5 June 2017).

NCT03196024 *{published data only}*

NCT03196024. Corazon de la Familia (Heart of the Family). clinicaltrials.gov/show/NCT03196024 (first received 20 June 2017).

NCT03317977 *{published data only}*

NCT03317977. Translating an efficacious illness management intervention for youth with asthma. clinicaltrials.gov/show/NCT03317977 (first received 18 October 2017).

NCT03699748 *{published data only}*

NCT03699748. Lay health worker engage, educate, and encourage patients to share. clinicaltrials.gov/study/NCT03699748 (first received 5 October 2018).

NCT03800459 *{published data only}*

NCT03800459. Effect of a family empowerment program on coping, problem solving in parents, and quality of life in children with cystic fibrosis. clinicaltrials.gov/show/NCT03800459 (first received 28 December 2018).

NCT03989986 *{published data only}*

NCT03989986. iPeer2Peer program for youth with sickle cell disease. clinicaltrials.gov/show/NCT03989986 (first received 17 June 2019).

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT03995953 *{published data only}*

NCT03995953. Integrated care delivery of HIV prevention and treatment in AGYW in Zambia. clinicaltrials.gov/show/NCT03995953 (first received 21 June 2019).

NCT04115813 *{published data only}*

NCT04115813. Project YES! Youth engaging for success. clinicaltrials.gov/show/NCT04115813 (first received 2 October 2019).

NCT04388592 *{published data only}*

NCT04388592. The effect of nurse practitioner (NP-led) care on mood, anxiety and health related quality of life in people with multiple sclerosis – a randomized trial. clinicaltrials.gov/show/NCT04388592 (first received 11 May 2020).

NCT04414553 *{published data only}*

NCT04414553. Community active and healthy families. clinicaltrials.gov/study/NCT04414553 (first received 20 May 2020).

NCT04761016 *{published data only}*

NCT04761016. The integrated population (I-POP) health trial. clinicaltrials.gov/study/NCT04761016 (first received 28 January 2021).

NCT04790604 *{published data only}*

NCT04790604. ENCOMPASS: expansion study A, RCT. clinicaltrials.gov/show/NCT04790604 (first received 13 January 2021).

NCT04790617 *{published data only}*

NCT04790617. ENCOMPASS: expansion study B, RCT. clinicaltrials.gov/show/NCT04790617 (first received 13 January 2021).

NCT04791267 *{published data only}*

NCT04791267. ENCOMPASS: expansion study C, RCT. clinicaltrials.gov/show/NCT04791267 (first received 5 May 2021).

NCT05292365 *{published data only}*

NCT05292365. Respiratory exacerbation plans for action and care transitions for children with severe CP. clinicaltrials.gov/study/NCT05292365 (first received 14 March 2022).

NCT05455216 *{published data only}*

NCT05455216. Peer caregiver navigation for family caregivers in oncology. ichgcp.net/clinical-trials-registry/NCT05455216 (first received 1 July 2022).

Overbury 2021 *{published data only}*

Overbury RS, Huynh K, Bohnsack J, Frech T, Hersh A. A novel transition clinic structure for adolescent and young adult patients with childhood onset rheumatic disease improves transition outcomes. *Pediatric Rheumatology Online Journal* 2021;**19**(1):164.

Pape 2022 *{published data only}*

Pape L, Kreuzer M, Großhenig A, Prüfe J, Group S. Health care transition of adolescents after kidney transplantation in Germany and Austria – the randomized controlled transnephro trial. *American Journal of Transplantation* 2022;**22**:694-5.

Parker 2008 *{published data only}*

Parker EA, Israel BA, Robins TG, Mentz G, Xihong Lin, Brakefield-Caldwell W, et al. Evaluation of Community Action Against Asthma: a community health worker intervention to improve children's asthma-related health by reducing household environmental triggers for asthma. *Health Education & Behavior* 2008;**35**(3):376-95.

Perry 2000 *{published data only}*

Perry CS, Toole KA. Impact of school nurse case management on asthma control in school-aged children. *Journal of School Health* 2000;**70**(7):303-4.

Plant 2015 *{published data only}*

Plant NA, Kelly PJ, Leeder SR, D'Souza M, Mallitt KA, Usherwood T, et al. Coordinated care versus standard care in hospital admissions of people with chronic illness: a randomised controlled trial. *Medical Journal of Australia* 2015;**203**(1):33-8.

Raphael 2013 *{published data only}***https://dx.doi.org/10.1016/j.acap.2013.04.015**

Raphael JL, Rueda A, Lion KC, Giordano TP. The role of lay health workers in pediatric chronic disease: a systematic review. *Academic Pediatrics* 2013;**13**(5):408-20. [DOI: 10.1016/j.acap.2013.04.015]

Robertson 1998 *{published data only}*

Robertson J. Stress point interventions for parents of children in hospital with chronic conditions reduced stress and improved child and family functioning [commentary on Burke SO, Handley-Derry MH, Costello EA, et al Stress-point intervention for parents of repeated]. *Evidence Based Nursing* 1998;**1**(3):79.

Saarijarvi 2021 *{published data only}*

Saarijarvi M, Wallin L, Moons P, Gyllensten H, Bratt EL. Mechanisms of impact and experiences of a person-centred transition programme for adolescents with CHD: the Stepstones project. *BMC Health Services Research* 2021;**21**(1):573.

Saarijarvi 2022 *{published data only}*

Saarijarvi M, Bratt EL, Moons P, Wallin L, Gyllensten H. Cost-effectiveness of a transition program for adolescents with congenital heart disease: the stepstones project. *Cardiology in the Young* 2022;**32**:S274-5.

Sequeira 2015 *{published data only}*

Sequeira PA, Pyatak EA, Weigensberg MJ, Vigen CP, Wood JR, Ruelas V, et al. Let's empower and prepare (LEAP): evaluation of a structured transition program for young adults with type 1 diabetes. *Diabetes Care* 2015;**38**(8):1412-9.

Sparring 2018 *{published data only}*

Sparring V, Tschank J, Handler K, Mansoory E, Konzett-Smoliner S, Lindgren P. Social and economic impact of a case management approach for people with rare and complex conditions in Salaj, Romania. *International Journal of Integrated Care* 2018;**18**:1-3.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Steinbeck 2012 *{published data only}*

Steinbeck KS, Harvey V, Shrewsbury VA, Donaghue K, Woodhead H. 132 outcomes for adolescents with type 1 diabetes mellitus participating in a comprehensive program to aid transition from pediatric to adult care: a pilot randomized controlled trial. *Journal of Adolescent Health* 2012;**50**(2):S77.

Sullivan-Bolyai 2010 *{published data only}***10.1177/0145721709352384**

Sullivan-Bolyai S, Bova C, Leung K, Trudeau A, Lee M, Gruppuso P. Social Support to Empower Parents (STEP): an Intervention for parents of young children newly diagnosed with type 1 diabetes. *Diabetes Educator* 2010;**36**(1):88-97.

Sullivan-Bolyai S, Grey M, Deatrick J, Gruppuso P, Giraitis P, Tamborlane W. Helping other mothers effectively work at raising young children with type 1 diabetes. *Diabetes Educator* 2004;**30**(3):476-84.

Takaro 2004 *{published data only}*

Takaro TK, Krieger JW, Song L. Effect of environmental interventions to reduce exposure to asthma triggers in homes of low-income children in Seattle. *Journal of Exposure Analysis and Environmental Epidemiology* 2004;**14**(Suppl 1):S133-43.

Thomsen 2022 *{published data only}*

Thomsen EL, Boisen KA, Hanghoj S, Hansson H, Grabow Scheelhardt HV, Christensen ST, et al. A comprehensive transfer program from pediatrics to adult care for parents of adolescents with chronic illness (ParTNerSTEPs): study protocol for a randomized controlled trial. *Trials* 2022;**23**(1):1034.

Tschank 2018 *{published data only}***10.1186/s13023-018-0895-2**

Tschank J, Handler K, Konzett-Smoliner S. Measuring the effects of a case management approach on the quality of life of rare and complex disease patients in Salaj, Romania: a pilot randomised control trial of efficacy. *Orphanet Journal of Rare Diseases* 2018;**13**:P38. [DOI: 10.1186/s13023-018-0895-2]

Yang 2022 *{published data only}*

Yang J, Lin L, Gao Y, Wang W, Yuan L. Interventions and strategies to improve social support for caregivers of children with chronic diseases: an umbrella review. *Frontiers in Psychiatry* 2022;**13**:973012.

Yun 2015 *{published data only}*

Yun L, Boles RE, Haemer MA, Knierim S, Dickinson LM, Mancinas H, et al. A randomized, home-based, childhood obesity intervention delivered by patient navigators. *BMC Public Health* 2015;**15**:506.

References to studies awaiting assessment

ACTRN12622001459718 *{published data only}***12622001459718**

ACTRN12622001459718. Equity pathways in integrated care in cerebral palsy (EPIC-CP): a pilot clinical trial of social prescribing for children and young people with cerebral palsy and their parents/caregivers. www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=384867 (first received 27 October 2022).

Goyal 2022 *{published data only}***10.1016/j.cct.2022.106830CTRI/2020/10/028379**

Goyal A, Peerzada A, Sarteau AC, Praveen PA, Kalaivani M, Tandon N. A multi-center pediatric to adult care transition intervention program to improve clinic visit adherence and clinical outcomes among adolescents and emerging adults with type 1 diabetes mellitus [PATHWAY]: protocol for a randomized controlled trial. *Contemporary Clinical Trials* 2022;**119**:106830. [DOI: 10.1016/j.cct.2022.106830]

NCT05353998 *{published data only}*

NCT05353998. Efficacy of clinical decision support and sleep navigation (sleep PASS). clinicaltrials.gov/study/NCT05353998 (first received 15 March 2022). [NCT: NCT05353998]

NCT05639088 *{published data only}*

NCT05639088. Improving transition care for adolescents and young adults with type 1 diabetes (SHIFT2). clinicaltrials.gov/study/NCT05639088 (first received 28 November 2022). [CLINICAL TRIALS NUMBER: NCT05639088]

Willems 2021 *{published data only}***10.3389/fped.2021.614512**

Willems J, Farin-Glattacker E, Langer T. Evaluation of a case management to support families with children diagnosed with spinal muscular atrophy – protocol of a controlled mixed-methods study. *Frontiers in Pediatrics* 2021;**9**:614512.

References to ongoing studies

Bollegala 2022 *{published data only}***10.1186/s12876-022-02307-9**

Bollegala N, Barwick M, Fu N, Griffiths AM, Keefer L, Ahola Kohut S, et al. Multimodal intervention to improve the transition of patients with inflammatory bowel disease from pediatric to adult care: protocol for a randomized controlled trial. *BMC Gastroenterology* 2022;**22**:251. [DOI: 10.1186/s12876-022-02307-9]

NCT05221281. Implementing a multimodal RCT intervention to improve the transition of patients with Crohn's disease from pediatric to adult care. clinicaltrials.gov/study/NCT05221281 (first received 10 January 2022). [CLINICALTRIALS.GOV: NCT05221281]

Bryant-Stephens 2021 *{published data only}***10.1016/j.conctc.2021.100864**

Bryant-Stephens T, Williams Y, Kanagasundaram J, Apter A, Kenyon CC, Shultz J. The West Philadelphia asthma care implementation study. *Contemporary Clinical Trials Communications* 2021;**24**:100864.

Jimenez 2021 *{published data only}*

Jimenez N, Fuentes M, Virtue A, Alonso-Gonzalez L, Lopez E, Zhou C, et al. Feasibility and acceptability of a telephone-based intervention for Hispanic children to promote treatment adherence after traumatic brain injury: a pilot study. *Journal of Head Trauma Rehabilitation* 2021;**36**(4):274-81. [DOI: 10.1097/HTR.0000000000000658]

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Lipman 2019 *{published data only}*10.1016/j.pedn.2019.08.014

Lipman TH, Smith JA, Hawkes CP. Community health workers and the care of children with type 1 diabetes. *Journal of Pediatric Nursing* 2019;**49**:111-2. [DOI: 10.1016/j.pedn.2019.08.014]

NCT01834456 *{published data only}*

NCT01834456. Comprehensive care of children with medical complexity. clinicaltrials.gov/study/NCT01834456 (first received 21 December 2012). [CLINICAL TRIALS NUMBER: NCT01834456]

NCT03648710 *{published data only}*

NCT03648710. Community health workers and mhealth for sickle cell disease care. clinicaltrials.gov/study/NCT03648710 (first received 24 August 2018). [CLINICAL TRIALS NUMBER: NCT03648710]

NCT04238949 *{published data only}*10.1016/j.pedn.2019.08.014

NCT04238949. Community health workers in pediatric patients with newly diagnosed type 1 diabetes. clinicaltrials.gov/study/NCT04238949 (first received 21 January 2020).

NCT05294042 *{published data only}*

NCT05294042. Patient navigators for children's community mental health services in high poverty urban communities. clinicaltrials.gov/study/NCT05294042 (first received 2 February 2022).

Orkin 2019 *{published data only}*

Orkin J, Chan CY, Fayed N, Lin JL, Major N, Lim A, et al. Complex care for kids Ontario: protocol for a mixed-methods randomised controlled trial of a population-level care coordination initiative for children with medical complexity. *BMJ Open* 2019;**9**:e028121. [DOI: 10.1136/ bmjopen-2018-028121]

Samuel 2019 *{published data only}*

NCT03342495. Evaluating innovations in transition from pediatric to adult care – the Transition Navigator trial. clinicaltrials.gov/study/NCT03342495 (first received 3 November 2017). [CLINICALTRIALS.GOV: NCT03342495]

Samuel S, Dimitropoulos G, Schraeder K, Klarenbach S, Nettel-Aguirre A, Guilcher G, et al. Pragmatic trial evaluating the effectiveness of a patient navigator to decrease emergency room utilisation in transition age youth with chronic conditions: the Transition Navigator Trial protocol. *BMJ Open* 2019;**9**(12):e034309. [DOI: 10.1136/bmjopen-2019-034309]

Smaldone 2019 *{published data only}*

Smaldone A, Manwani D, Aygun B, Smith-Whitley K, Jia H, Bruzzese J-M, et al. HABIT efficacy and sustainability trial, a multi-center randomized controlled trial to improve hydroxyurea adherence in youth with sickle cell disease: a study protocol. *BMC Pediatrics* 2019;**19**:354. [DOI: 10.1186/s12887-019-1746-6]

van Zwieten 2019 *{published data only}***ACTRN12618001152213**

Guha C, Khalid R, van Zweiten A, Francis A, Hawley CM, Jaure A, et al. Baseline characteristics of participants in the NAVKIDS2 trial: a patient navigator program in children with chronic kidney disease. *Pediatric Nephrology (Berlin, Germany)* 2023;**38**(5):1577-90. [DOI: 10.1007/s00467-022-05772-2]

van Zwieten A, Caldwell P, Howard K, Tong A, Craig JC, Alexander S, et al. NAV-KIDS2 trial: protocol for a multi-centre, staggered randomised controlled trial of a patient navigator intervention in children with chronic kidney disease. *BMC Nephrology* 2019;**20**:134. [ACTRN: 12618001152213] [DOI: 10.1186/s12882-019-1325-y]

van Zwieten A, Ryan EG, Caldwell P, Howard K, Tong A, Craig JC, et al. NAVKIDS2 trial: a multi-centre, waitlisted randomised controlled trial of a patient navigator intervention in children with chronic kidney disease – statistical analysis plan and update to the protocol. *Trials* 2022;**23**:824.

Wahi 2022 *{published data only}*10.1186/s14-2022-01080-6

Wahi G, Marjerrison S, Gutierrez C, Krasevich K, Morrison KM, Thabane L. Screening and addressing social needs of children and families enrolled in a pediatric weight management program: a protocol for a pilot randomized controlled trial. *Pilot and Feasibility Studies* 2022;**8**:129.

Additional references

Algurén 2021

Algurén B, Ramirez JP, Salt M, Sillett N, Myers SN, Alvarez-Cote A, et al. Development of an international standard set of patient-centred outcome measures for overall paediatric health: a consensus process. *Archives of Disease in Childhood* 2021;**106**:868-76.

Australian Institute of Health and Welfare 2020

Australian Institute of Health and Welfare, Australian Government. Chronic disease. www.aihw.gov.au/reports-data/health-conditions-disability-deaths/chronic-disease/overview (accessed prior to 13 August 2024).

Bennett 1994

Bennett DS. Depression among children with chronic medical problems: a meta-analysis. *Journal of Pediatric Psychology* 1994;**19**(2):149-69.

Borenstein 2009

Borenstein M, Hedges LV, Higgins JP, Rothstein HR. When does it make sense to perform a meta-analysis? In: Introduction to Meta-Analysis. Chichester, UK: John Wiley & Sons, Ltd, 2009:357-64.

Bregnballe 2007

Bregnballe V, Thastum M, Schiotz PO. Psychosocial problems in children with cystic fibrosis. *Acta Paediatrica* 2007;**96**(1):58-61.

Callahan 2001

Callahan ST, Winitzer RF, Keenan P. Transition from pediatric to adult-oriented health care: a challenge for patients with chronic disease. *Current Opinion in Pediatrics* 2001;**13**(4):310-6.

Carroll 2010

Carroll J, Humiston S, Meldrum S, Salamone C, Jean-Pierre P, Epstein R, et al. Patients' experiences with navigation for cancer

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

care. *Patient Education and Counselling* 2010;**80**(2):241-7. [DOI: 10.1016/j.pec.2009.10.024]

Carter 2018

Carter N, Valaitis RK, Lam A, Feather J, Nicholl J, Cleghorn L. Navigation delivery models and roles of navigators in primary care: a scoping literature review. *BMC Health Services Research* 2018;**18**(1):1-3. [DOI: 10.1186/s12913-018-2889-0]

Carter 2022

Carter HE, Waugh J, Chang AB, Shelton D, David M, Weir KA, et al. Cost-effectiveness of care coordination for children with chronic noncomplex medical conditions: results from a multicenter randomized clinical trial. *Value in Health* 2022;**22**:S1098-3015. [DOI: 10.1016/j.jval.2022.06.008]

Caskey 2019

Caskey R, Moran K, Touchette D, Martin M, Munoz G, Kanabar P, et al. Effect of comprehensive care coordination on Medicaid expenditures compared with usual care among children and youth with chronic disease: a randomized clinical trial. *JAMA Network Open* 2019;**2**(10):e1912604.

CDC 2021

Centers for Disease Control and Prevention. National Centre for Chronic Disease Prevention and Health Promotion – about chronic disease. www.cdc.gov/chronicdisease/about/index.htm (accessed 12 January 2021).

Chu 2015

Chu PY, Maslow GR, von Isenburg M, Chung RJ. Systematic review of the impact of transition interventions for adolescents with chronic illness on transfer from pediatric to adult healthcare. *Journal of Pediatric Nursing* 2015;**30**(5):e19-27. [DOI: 10.1016/j.pedn.2015.05.022]

Cohen 2018

Cohen S, Earing MG. Neurocognitive impairment and its long-term impact on adults with congenital heart disease. *Progress in Cardiovascular Diseases* 2018;**61**(3-4):287-93.

Conn 2019

Conn S, Curtain S. Health coaching as a lifestyle medicine process in primary care. *Australian Journal of General Practitioners* 2019;**48**(10):677-80.

Council on Community Pediatrics 2016

Council on Community Pediatrics. Poverty and child health in the United States. Pediatrics 2016;**137**(4):e20160339. [DOI: 10.1542/peds.2016-0339]

D'Zurilla 1971

D'Zurilla TJ, Goldfried MR. Problem solving and behavior modification. *Journal of Abnormal Psychology* 1971;**78**:107-26.

Desveaux 2019

Desveaux L, McBrien K, Barnieh L, Ivers N. Mapping variation in intervention design: a systematic review to develop a program theory for patient navigator programs. *Systematic Reviews* 2019;**8**(1):1-14. [DOI: 10.1186/s13643-018-0920-5]

Dohan 2005

Dohan D, Schrag D. Using navigators to improve care of underserved patients: current practices and approaches. *Cancer* 2005;**104**(4):848-55. [DOI: 10.1002/cncr.21214]

EPOC 2017a

Cochrane Effective Practice and Organisation of Care (EPOC). Data collection form. EPOC resources for review authors, 2017. epoc.cochrane.org/epoc-specific-resources-review-authors (accessed 2 February 2021).

EPOC 2017b

Cochrane Effective Practice and Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC resources for review authors, 2017. epoc.cochrane.org/epoc-specific-resources-review-authors (accessed 2 February 2021).

EPOC 2017c

Cochrane Effective Practice and Organisation of Care (EPOC). EPOC worksheets for preparing a summary of findings table using GRADE. EPOC resources for review authors, 2017. epoc.cochrane.org/epoc-specific-resources-review-authors (accessed 3 February 2021).

Feinberg 2016

Feinberg E, Abufhele M, Sandler J, Augustyn M, Cabral H, Chen N, et al. Reducing disparities in timely autism diagnosis through family navigation: results from a randomized pilot trial. *Psychiatric Services (Washington, D.C.)* 2016;**67**(8):912-5. [DOI: 10.1176/appi.ps.201500162]

Francis 2019

Francis A, Didsbury MS, van Zwieten A, Chen K, James LJ, Kim S, et al. Quality of life of children and adolescents with chronic kidney disease: a cross-sectional study. *Archives of Disease in Childhood* 2019;**104**:134-40. [10.1136/archdischild-2018-314934]

Freeman 2005

Freeman HP, Chu KC. Determinants of cancer disparities: barriers to cancer screening, diagnosis, and treatment. *Surgical Oncology Clinics of North America* 2005;**14**(4):655-9.

Global Burden of Disease 2019

Global Burden of Disease 2019 Cancer Collaboration. Cancer incidence, mortality, years of life lost, years lived with disability, and disability-adjusted life years for 29 cancer groups from 2010 to 2019: a systematic analysis for the Global Burden of Disease Study 2019. *JAMA Oncology* 2022;**8**(3):420-44. [DOI: 10.1001/jamaoncol.2021.6987]

Gomersall 2015

Gomersall JS, Jadotte YT, Xue Y, Lockwood S, Riddle D, Preda A. Conducting systematic reviews of economic evaluations. *International Journal of Evidence-Based Healthcare* 2015;**13**(3):170-8. [DOI: 10.1097/XEB.0000000000000063]

Gottlieb 2016

Gottlieb LM, Hessler D, Long D, Laves E, Burns AR, Amaya A, et al. Effects of social needs screening and in-person service navigation on child health: a randomized clinical trial. *JAMA Pediatrics* 2016;**170**(11):e162521.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

GRADEpro GDT [Computer program]

GRADEpro GDT. Version accessed 30 January 2023. Hamilton (ON): McMaster University (developed by Evidence Prime), 2023. Available at https://www.gradepro.org.

Guyatt 2008

Guyatt GH, Oxman AD, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al, GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ (Clinical Research Ed.)* 2008;**336**(7650):924-6.

Higgins 2011

Higgins JP, Altman DG, Sterne JA. Chapter 8: Assessing risk of bias in included studies. In: Higgins JP, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from training.cochrane.org/handbook/archive/v5.1/.

Higgins 2020a

Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 6.1 (updated September 2020). Cochrane, 2020. Available from training.cochrane.org/handbook/archive/v6.1.

Higgins 2020b

Higgins JP, Eldridge S, Li T. Chapter 23: Including variants on randomized trials. In: Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 6.1 (updated September 2020). Cochrane, 2020. Available from training.cochrane.org/handbook/archive/v6.1.

Jandorf 2013

Jandorf L, Stossel L, Cooperman L, Graff Zivin J, Ladabaum J, Hall U, et al. Cost analysis of a patient navigation system to increase screening colonoscopy adherence among urban minorities. *Cancer* 2013;**119**(3):612-20.

Kelly 2015

Kelly E, Ivers N, Zawi R, Barnieh L, Manns B, Lorenzetti DL, et al. Patient navigators for people with chronic disease: protocol for a systematic review and meta-analysis. *Systematic Reviews* 2015;**4**(1):1-6.

Kelly 2019

Kelly K, Doucet S, Luke A. Exploring the roles, functions, and background of patient navigators and case managers: a scoping review. *International Journal of Nursing Studies* 2019;**98**:27-47. [DOI: 10.1016/j.ijnurstu.2019.05.016]

Krieger 2009

Krieger J, Takaro T, Song L, Beaudet N, Edwards K. A randomized controlled trial of asthma self-management support comparing clinic-based nurses and in-home community health workers: the Seattle-King County healthy homes II project. *Archives of Pediatrics & Adolescent Medicine* 2009;**163**(2):141-9.

Kuenzig 2022

Kuenzig ME, Fung SG, Marderfeld L, Mak JW, Kaplan GG, Ng SC, et al. Twenty-first century trends in the global epidemiology of pediatric-onset inflammatory bowel disease: systematic review. *Gastroenterology* 2022;**162**(4):1147-59.e4. [DOI: 10.1053/j.gastro.2021.12.282]

Liberati 2009

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLOS Medicine* 2009;**6**(7):e1000100.

Lähteenmäki 2004

Lähteenmäki PM, Sjöblom J, Korhonen T, Salmi TT. The siblings of childhood cancer patients need early support: a follow up study over the first year. *Archives of Disease in Childhood* 2004;**89**(11):1008-13.

Marmot 2012

Marmot M, Bell R. Fair society, healthy lives. *Public Health* 2012;**126**(Suppl 1):S4-10.

McBrien 2018

McBrien KA, Ivers N, Barnieh L, Bailey JJ, Lorenzetti DL, Nicholas D, et al. Patient navigators for people with chronic disease: a systematic review. *PLOS One* 2018;**13**(2):e0191980. [DOI: 10.1371/journal.pone.0191980]

McDonald 2004

McDonald SP, Craig JC, the Australian and New Zealand Paediatric Nephrology Association. Long-term survival of children with end-stage renal disease. *New England Journal of Medicine* 2004;**350**(26):2654-62. [DOI: 10.1056/NEJMoa031643]

Medway 2015

Medway M, Tong A, Craig JC, Kim S, Mackie F, McTaggart S, et al. Parental perspectives on the financial impact of caring for a child with CKD. *American Journal of Kidney Diseases* 2015;**65**(3):384-93.

Morgan 2013

Morgan S, Rahman C, Alqatari A, Pines M, Jesse M. Non-emergency department interventions to reduce ED utilization: a systematic review. *Academic Emergency Medicine* 2013;**20**(10):969-85.

Natale-Pereira 2011

Natale-Pereira A, Enard KR, Nevarez L, Jones LA. The role of patient navigators in eliminating health disparities. *Cancer* 2011;**117**(15):3543-52.

Pantell 2020

Pantell MS, Hessler D, Long D, Alqassari M, Schudel C, Laves E, et al. Effects of in-person navigation to address family social needs on child health care utilization: a randomized clinical trial. JAMA Network Open 2020;**3**(6):e206445. [DOI: 10.1001/jamanetworkopen.2020.6445]

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Perrin 2014

Perrin J, Anderson E, van Cleave J. The rise in chronic conditions among young infants, children and youth can be met with continued health system innovations. *Health Affairs* 2014;**33**(12):2099-105. [DOI: 10.1377/hlthaff.2014.0832]

Petereit 2008

Petereit DG, Molloy K, Reiner ML, Helbig P, Cina K, Miner R, et al. Establishing a patient navigator program to reduce cancer disparities in the American Indian communities of Western South Dakota: initial observations and results. *Cancer Control* 2008;**15**(3):254-9.

Quittner 2008

Quittner AL, Barker DH, Snell C, Grimley ME, Marciel K, Cruz I. Prevalence and impact of depression in cystic fibrosis. *Current Opinion in Pulmonary Medicine* 2008;**14**(6):582-8.

Resnick 2009

Resnick E, Bishop M, O'Connell A, Hugo B, Isern G, Timm A, et al. The CHEER study to reduce BMI in elementary school students: a school-based, parent-directed study in Framingham, Massachusetts. *Journal of School Nursing* 2009;**25**(5):361-72.

RevMan 2024 [Computer program]

Review Manager (RevMan). Version 7.12.0. The Cochrane Collaboration, 2024. Available at https://revman.cochrane.org.

Rodriguez-Torres 2019

Rodriguez-Torres SA, McCarthy AM, He W, Ashburner JM, Percac-Lima S. Long-term impact of a culturally tailored patient navigation program on disparities in breast cancer screening in refugee women after the program's end. *Health Equity* 2019;**3**(1):205-10.

Simon 2017

Simon TD, Whitlock KB, Haaland W, Wright DR, Zhou C, Neff J, et al. Effectiveness of a comprehensive case management service for children with medical complexity. *Pediatrics* 2017;**140**(6):e20171641. [DOI: 10.1542/peds.2017-1641]

Smith 2017

Smith LR, Clayton ML, Woodell C, Mansfield C. The Role of Patient Navigators in Improving Caregiver Management of Childhood Asthma. Research Triangle Park (NC): RTI Press, 2017. [DOI: 10.3768/ rtipress.2017.rr.0030.1704] [PMID: 30354041]

Spencer 2018

Spencer MS, Kieffer EC, Sinco B, Piatt G, Palmisano G, Hawkins J, et al. Outcomes at 18 months from a community health worker and peer leader diabetes self-management program for Latino adults. *Diabetes Care* 2018;**41**(7):1414-22. [DOI: 10.2337/dc17-0978]

Sterne 2011

Sterne JA, Sutton AJ, Ioannidis JP, Terrin N, Jones DR, Lau J, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ (Clinical Research Ed.)* 2011;**343**:d4002. [DOI: 10.1136/bmj.d4002]

Stoll 2010

Stoll BJ, Hansen NI, Bell EF. Neonatal outcomes of extremely preterm infants from the NICHD neonatal research network. *Pediatrics* 2010;**126**(3):443-56.

Thom 2013

Thom DH, Ghorob A, Hessler D, De Vore D, Chen E, Bodenheimer TA. Impact of peer health coaching on glycemic control in low-income patients with diabetes: a randomized controlled trial. *Annals of Family Medicine* 2013;**11**(2):137-44.

Tsai 2006

Tsai TC, Liu SI, Tsai JD, Chou LH. Psychosocial effects on caregivers for children on chronic peritoneal dialysis. *Kidney International* 2006;**70**(11):1983-7.

van Cleave 2010

van Cleave J, Gortmaker SL, Perrin JM. Dynamics of obesity and chronic health conditions among children and youth. *JAMA* 2010;**303**(7):623-30. [DOI: 10.1001/jama.2010.104]

Wells 2008

Wells KJ, Battaglia TA, Dudley DJ, Garcia R, Greene A, Calhoun E, et al. Patient Navigation Research Program. Patient navigation: state of the art or is it science? *Cancer* 2008;**113**(8):1999-2010.

Whiting-O'Keefe 1984

Whiting-O'Keefe Q, Henke C, Simborg D. Choosing the correct unit of analysis in medical care experiments. *Medical Care* 1984;**22**(12):1101-14.

WHO 2018

World Health Organization. Standards for improving the quality of care for children and young adolescents in health facilities. www.who.int/publications/i/item/9789241565554 (accessed 13 August 2024). [ISBN: 978 92 4 156555 4]

WHO 2019

World Health Organization. Integrated chronic disease prevention and control. www.who.int/chp/about/integrated_cd/en (accessed 3 January 2020).

WHO 2020

World Health Organization. Adolescent health. www.who.int/southeastasia/health-topics/adolescent-health (accessed 2 September 2020).

Wijlaars 2016

Wijlaars LP, Gilbert R, Hardelid P. Chronic conditions in children and young people: learning from administrative data. *Archives of Disease in Childhood* 2016;**101**(10):881-5.

Wilson 2019

Wilson T, Zhao Y, Condon J. Limited progress in closing the mortality gap for Aboriginal and Torres Strait Islander Australians of the Northern Territory. *Australian and New Zealand Journal of Public Health* 2019;**43**(4):340-5.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

References to other published versions of this review

Lalji 2021

Lalji R, Francis A, Khalid R, Guha C, Johnson DW, Wong G. Patient navigator programmes for children and adolescents with chronic diseases. *Cochrane Database of Systematic Reviews* 2021, Issue 7. Art. No: CD014688. [DOI: 10.1002/14651858.CD014688]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Flores 2009

Study characteristics	
Methods	Randomised controlled trial Allocation 1:1 Control: traditional asthma care Intervention: parent mentor Blinding: not to intervention, blinded to analysis of data Centre: Milwaukee, Wisconsin, USA Recruitment: February 2004 to May 2007 Follow-up: 12 months
Participants	Inclusion criteria: African American or Latino heritage, aged 2–18 years, primary diagnosis of asthma, living in Milwaukee Exclusion: significant comorbidities that might lead to ED presentations, enrolment in a competing asthma study Recruitment: from ED or hospital wards Setting: home visit, community centre, church, or family resource centre Location: Wisconsin Significant differences between groups at baseline: no **Baseline characteristics** (control: 108; intervention: 112) Age mean (years): control: 7.3 (SD 4.4); intervention: 7.1 (SD 4.3); P = 0.72 Female: control: 47.2%; intervention: 40.2%; P = 0.29 Limited English proficiency: control: 24.1%; intervention: 31.3%; P = 0.23 Smoking in household: control: 36.7%; intervention: 46.6%; P = 0.31 Asthma severity: • mild intermittent: control: 25%; intervention: 28.6% • mild persistent: control: 17.6%; intervention: 24.1% • moderate persistent: control: 13.0%; intervention: 13.4% • severe persistent: control: 44.4%; intervention: 33.9%; P = 0.4 Health insurance: • public: control: 79.6%; intervention: 86.6%

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Flores 2009 *(Continued)*

- private: control: 16.7%; intervention: 9.8%
- none: control: 2.8%; intervention: 2.7%
- other: control: 0.9%; intervention: 0.9%

Has asthma care plan: control: 48.1%; intervention: 39.6%; P = 0.45

Takes prescribed medication: control: 94.4%; intervention: 95.5%; P = 0.7

Asthma attacks in previous year, mean: control: 13.9 (SD 42.7); intervention: 10.4 (SD 36.0); P = 0.53

Doctor visits for asthma, mean: control: 6.7 (SD 10.8); intervention: 4.9 (SD 5.8); P = 0.13

ED visits for asthma, mean: control: 3.4 (SD 3.7); intervention: 3.1 (SD 3.4); P = 0.49

Hospitalisations for asthma: control: 0.6 (SD 1.1); intervention: 1.0 (SD 1.9); P = 0.11

ICU for asthma: control: 0.1 (SD 0.48); intervention: 0.1 (SD 0.44); P = 0.74

Asthma attacks in previous month: control: 2.2 (SD 4.1); intervention: 1.8 (SD 4.0); P = 0.41

Missed school days: control: 8.1 (SD 15.5); intervention: 6.8 (SD 10.9); P = 0.47

Parental missed work days: control: 7.3 (SD 14.4); intervention: 4.8 (SD 9.9); P = 0.17

Interventions	**Intervention** (112 participants): parent mentors received an intensive 2.5-day training session led by a nurse asthma specialist and programme co-ordinator and a 73-page training manual (in English and Spanish). In addition, parent mentors received training and resources on insurance programmes for uninsured children, locations of free clinics, medication and equipment teaching sheets, and creating reminder calendars for healthcare provider appointments. Training and resource manuals on assisting families with unmet needs for health insurance, housing, food, and other social concerns. Initial home visit, then monthly meetings at an assigned community learning centre, boys and girls club, church, or family resource centre. **Control** (108 participants): standard care
Outcomes	No specified primary outcomes • Frequency of child's symptoms and asthma exacerbations (self-report) • Missed school days (self-report) • Missed work days (self-report) • Paediatric Quality of Life Inventory • Paediatric Asthma Caregiver's Quality of Life Questionnaire • ED visits (self-report, confirmed by medical record review, computer surveillance) • Hospitalisations (self-report, monitoring of medical records and inpatient admission logs) • Parents Asthma Management Self-Efficacy Scale • Cost and cost-effectiveness outcomes – cost personnel, parent mentor stipend payments, parent mentor training sessions, monthly meetings with participants, cost of care charges. Incremental cost-effectiveness ratio is used to calculate cost-effectiveness.
Notes	Ethics: approved by the institutional review board of Children's Hospital Wisconsin, Aurora Health Care, and Wheaton Franciscan Health Care. Written consent obtained and child assent (when indicated) for all participants. Declarations of interests/disclosures: none reported. Funding: grants to authors from Commonwealth Fund and Improving Chronic Illness Care programme of Robert Wood Johnson Foundation. Trial registration or protocol registration or publication: NCT00800020.

Risk of bias

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Flores 2009 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "participants were randomly assigned to C [control] or I [intervention] group using SAS 9.1.3." Comment: did not explain how this was done.
Allocation concealment (selection bias)	Unclear risk	No further information provided regarding allocation concealment and if this could be predicted.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants could not be blinded to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "a research assistant who was blinded to the group allocation assessed 10 outcomes for 12 months using standardized telephone interview methods with parents." Comment: risk of participant inadvertently disclosing group allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "See figure 1 flow diagram: 45 (40%) dropped out/withdrew after assignment to intervention, 44 (41%) dropped out/withdrew after assignment to control. All included in primary analysis (intention to treat)." Comment: some data provided regarding exclusion data but not attrition data once enroled in study. Comparable between both groups (40% dropout/withdrawals from intervention, 41% from control). Study did calculate sample size of 220 based on anticipated attrition rate (power 80%, alpha = 0.05, lambda = 20%). No explanation provided regarding dropout reasons.
Selective reporting (reporting bias)	Low risk	Trial registration details provided.
Baseline outcomes measurement	Low risk	Quote: "No significant baseline intergroup differences existed for any parent (Table 1) or child (Table 2) characteristic."
Baseline characteristics	Low risk	Quote: "No significant baseline intergroup differences existed for any parent (Table 1) or child (Table 2) characteristic."
Other bias	Unclear risk	No conflict of interests declared by authors. Standard care group was paid for their participation in the study: USD 50 initially and then USD 10/visit ongoing. No mention of whether intervention was paid (however, the fact that the standard group had financial incentive might explain why this group also improved in some of the study outcomes). Ethics: approved by institutional review board of Children's Hospital Wisconsin, Aurora Health Care and Wheaton Franciscan Health Care. Written consent obtained and child assent (when indicated) for all participants. Declarations of interests/disclosures: none reported. Funding: grants to authors from Commonwealth Fund and Improving Chronic Illness Care programme of Robert Wood Johnson Foundation. Trial registration or protocol registration or publication: NCT00800020.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frakking 2022

Study characteristics	
Methods	Parallel study design, randomised controlled Allocation: 1:1 Controlled: yes Blinding: no (not to intervention) Arms: control (standard care); intervention (care co-ordination) Centres: Caboolture Hospital, Gold Coast University Hospital, and Queensland Children's Hospital Dates and follow-up: from October 2017 to October 2020; 12 months' follow-up
Participants	Inclusion criteria: aged 0–16 years; newly diagnosed with a developmental chronic condition where community-based health or family support services were part of the management plan; chronic conditions expected to last > 6 months, and to produce consequences that impacted on the child's quality of life; examples of developmental chronic conditions include (but were not limited to): autism spectrum disorder, attention deficit hyperactivity disorder, intellectual impairment, specific language impairment, oppositional defiance disorder, foetal alcohol spectrum disorder, cerebral palsy Exclusion criteria: children with acute medical conditions requiring urgent intervention where community follow-up was deemed inappropriate by the treating paediatrician; children with a chronic medical condition primarily managed by medical consultation alone and those conditions where hospital-based multidisciplinary teams provided co-ordinated care; examples of excluded chronic conditions included: cancer, cystic fibrosis, asthma, epilepsy Recruitment: October 2017 to October 2019 **Baseline characteristics** Intervention: 42 children/adolescents vs control: 39 children/adolescents ***Children*** Age, mean (years): intervention: 8.6 (SD 3.6); control: 7.8 (SD 3.4) Sex: female: intervention: 14/42 (33.3%); control: 12/39 (30.8%); male: intervention: 28/42 (66.7%); control: 27/39 (69.2%) New diagnosis • Attention-deficit disorder/hyperactivity disorder: intervention: 24/42 (57.1%); control: 23/39 (59%) • Autism spectrum disorder: intervention: 9/42 (21.4%); control: 11/39 (28.2%) • Other[a]: intervention: 9/42 (21.4%); control: 5/39 (12.8%) School level • Childcare: intervention: 9/39 (23.1%); control: 14/35 (40%) • Primary: intervention: 21/39 (53.9%); control: 16/35 (45.7%) • Secondary: intervention: 9/39 (23.1); control: 5/35 (14.3%) ***Caregivers*** Highest education level • Primary: intervention: 9/42 (21.4%); control: 3/34 (8.8%) • Secondary: intervention: 16/42 (38.1); control: 12/34 (35.3%) • Technical and further education: intervention: 16/42 (38.1%); control: 15/34 (44.1%) • Tertiary: intervention: 1/42 (2.4%); control: 4/34 (11.8%)

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frakking 2022 *(Continued)*

Employment status

- Employed: intervention: 19/42 (45.2%); control: 21/34 (61.8%)
- Not employed: intervention: 23/42 (54.8%); control: 13/34 (38.2%)

Self-identified mental health condition

- No: intervention: 19/42 (45.2%); control: 17/34 (50.0%)
- Yes: intervention: 23/42 (54.8%); control: 17/34 (50.0%)

Site

- Caboolture Hospital: intervention: 25/42 (59.5%); control: 21/39 (53.8%)
- Gold Coast University Hospital: intervention: 12/42 (28.6%); control: 13/39 (33.3%)
- Queensland Children's Hospital: intervention: 5/42 (11.9%); control: 5/39 (12.8%)

[a]Other diagnoses include global developmental delay, oppositional defiant disorder, adjustment disorder, and generalised anxiety disorder.

Interventions	Prerandomisation: 81 participants **Intervention group** (42 participants): integrated care co-ordination. 1 allied health liaison officer for all 3 sites (speech pathologist with clinical experience in multidisciplinary assessment and intervention of paediatric neurological conditions). The officer was responsible for communication with the children and their caregivers to ascertain their priorities in healthcare access across hospital, education, primary care, and community sectors for the duration of their participation in the trial. Frequency of communication varied amongst participants and was determined by the individual preferences of each caregiver. Examples of activities undertaken by the officer included co-ordination of multidisciplinary team meetings in the primary care and education sectors, assistance with health literacy and advocacy (e.g. navigation of different funding schemes and support, service linkages, assistance with completion of forms, and provision of health literacy brokerage across sectors and internal to the hospital), and co-ordination of healthcare appointment scheduling. **Control group** (39 participants): standard care. Participants and their families who received standard care were not provided access to an allied health liaison officer. Caregivers independently sought assistance with management of their child's chronic condition using standard systems and resources across the primary care, education, community, and hospital sectors. The frequency of reviews with a primary care physician was individually determined by each caregiver with no standardised time points in the participant's healthcare experience. Co-interventions or additional treatments: none Duration of treatments and follow-up details: 12-month intervention and follow-up (postrecruitment).
Outcomes	**Primary outcomes** • Paediatric Quality of Life Inventory – Child – score 0–100 (parent or child completed) • Paediatric Quality of Life Inventory – Family Impact – score 0–100 (parent completed) • Subjective Units of Distress Scale – score 0–100 (parent completed) • Rotter's Locus of Control Scale – score 0–23 (parent completed) **Secondary outcomes** • Number of general practitioner visits • Number of hospital admissions • Number of specialist appointments • Number of absent school days • Number of caregiver missed employment days based on parental report • Number of school suspensions, measured in days • Number of services accessed at the time, based on parental report

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frakking 2022 *(Continued)*

Notes	Ethics: approved by Children's Health Queensland, the Department of Human Services, and the Queensland Government Department of Education and Training ethics review committees. Parents or guardians provided written informed consent. The trial followed the CONSORT reporting guideline. Declarations of interests/disclosures: Dr Frakking reported receiving the Queensland Health 2017 Allied Health Professions of Queensland–Health Practitioner Research Scheme, the Children's Hospital Foundation 2019 Health Services Research grant, and a Prince Charles Hospital Foundation 2018 Caboolture Hospital Small Research grant during the conduct of the study and being supported by a Metro North Clinician Researcher Fellowship outside the submitted work. Dr Levitt reported receiving a Children's Hospital Foundation 2019 Health Services Research grant during the conduct of the study and a Children's Hospital Foundation 2019 Health Services Research grant outside the submitted work. Dr Chang reported receiving grants from the National Health and Medical Research Council during the conduct of the study. Dr Carter reported receiving grants from the Children's Hospital Foundation during the conduct of the study. Dr Waugh reported receiving a Queensland Health Government grant for health practitioner research, grants from the Children's Hospital Foundation, and grants from the Prince Charles Hospital Foundation during the conduct of the study. No other disclosures were reported. Funding: supported by the Allied Health Professions of Queensland–Health Practitioner Research Scheme (Dr Frakking), Children's Hospital Foundation (Dr Frakking), and Prince Charles Hospital Foundation (Dr Frakking). Trial registration or protocol registration or publication: ACTRN12617001188325.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned 1:1 using a permuted block design (with a block size of 2) to receive integrated care co-ordination or standard care.
Allocation concealment (selection bias)	Low risk	Intervention was randomly allocated to enroled participants from concealed, sequentially numbered opaque envelopes immediately after informed consent was obtained.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding in this trial was not possible owing to the nature of care co-ordination.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The research assistant was blinded to group allocation for all participants for the purposes of independent collection of measures at the 1-week, 3-month, 6-month, and 12-month telephone review time points.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of the 81 children randomised, 57 (70.4%) provided data at all 3 time points, 13 (16.0%) provided data at the first 2 time points, and 5 (6.2%) provided data only at baseline. All these children were included in the data analyses. However, 6 children provided no data after enrolment; therefore, the sample included in the data analysis was reduced from 81 to 75. Note: sample size calculation was 112 (assuming an attrition rate of 50%). Got to 81, 57 completed data for all 3 time points. Attrition rate for both groups was < 15%.
Selective reporting (reporting bias)	Low risk	Trial registration identifier: ACTRN12617001188325

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frakking 2022 *(Continued)*

Baseline outcomes measurement	Low risk	Study analysed change from baseline score to 6 months and 12 months from intervention. Differences between 2 study groups at baseline outcomes measurement was less likely to have an effect.
Baseline characteristics	Low risk	Quote: "Baseline characteristics were similar between the 2 groups (Table 1)."
Other bias	Low risk	The trial was approved by Children's Health Queensland, the Department of Human Services, and the Queensland Government Department of Education and Training ethics review committees. Parents or guardians provided written informed consent. The trial followed the CONSORT reporting guideline. Conflict of interest disclosures: Dr Frakking reported receiving the Queensland Health 2017 Allied Health Professions of Queensland–Health Practitioner Research Scheme, the Children's Hospital Foundation 2019 Health Services Research grant, and a Prince Charles Hospital Foundation 2018 Caboolture Hospital Small Research grant during the conduct of the study and being supported by a Metro North Clinician Researcher Fellowship outside the submitted work. Dr Levitt reported receiving a Children's Hospital Foundation 2019 Health Services Research grant during the conduct of the study and a Children's Hospital Foundation 2019 Health Services Research grant outside the submitted work. Dr Chang reported receiving grants from the National Health and Medical Research Council during the conduct of the study. Dr Carter reported receiving grants from the Children's Hospital Foundation during the conduct of the study. Dr Waugh reported receiving a Queensland Health Government grant for health practitioner research, grants from the Children's Hospital Foundation, and grants from the Prince Charles Hospital Foundation during the conduct of the study. No other disclosures were reported. Funding/support: supported by the Allied Health Professions of Queensland–Health Practitioner Research Scheme (Dr Frakking), Children's Hospital Foundation (Dr Frakking), and Prince Charles Hospital Foundation (Dr Frakking). Role of the funder/sponsor: funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Frantatoni 2022

Study characteristics	
Methods	Study design: randomised controlled trial Primary study: – Allocation: 1:1 Control: standard care Blinding: no Arms: intervention (parent navigator) vs control Centre: NICU of Children's National Health System in Washington DC. Covers Washington Metropolitan area (Maryland, Virginia, and DC) Dates and follow-up: enrolment January 2016 to February 2017. Follow-up to 12 months (duration of intervention)

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frantatoni 2022 *(Continued)*

Participants	Inclusion criteria: custodial parent of an infant in the NICU with planned discharge to home within 2 weeks; English speaking; parent aged ≥ 18 years; living within the Washington metropolitan area. 1 parent per infant to enrol Exclusion criteria: second parent not allowed to enrol for 1 infant Recruitment: NICU census reviewed daily, and chart review completed for each newly admitted patient. A database of all screened participants was created. NICU case managers met with research staff twice per week to determine eligible participants. A study recruitment flyer containing initial goals of study was used to introduce Giving Parents Support programme. Research staff followed up with interested families, either in person or by telephone. Setting: NICU Location: Washington Metropolitan Area Significant differences between groups at baseline: no **Baseline characteristics** Gestational age (weeks): control: 35.4 (SD 4.8); intervention: 35.7 (SD 4.8) NICU length of stay, mean (days): control: 34 (SD 38); intervention 35 (SD 40) Male: control: 58.7%; intervention: 57.3% Ethnicity • White: control: 37.3%; intervention: 40.7% • Black: control: 44%; intervention: 44.7% • Asian: control: 7.3%; intervention: 4% • American Indian or Pacific Islander: control: 4%; intervention: 1.3% • Mixed race: control: 7.3%; intervention: 9.3% • Hispanic or non-Hispanic: control: 8.7%; intervention: 6.7% Education • High school or less: control: 22.7%; intervention: 28.7% • Vocational/college: control: 30.7%; intervention: 27.3% • College or higher: control: 46.6%; intervention: 44.0% Relationship (single): control: 14.7%; intervention: 18.0% (remainder were married or partnered) Other children at home (none): control: 45.3%; intervention: 40.7% (remainder had ≥ 1) Baseline scale scores for Perceived Maternal Parenting Self Efficacy Scale; 10-item Perceived Stress Scale; Parental Stress Scale; State-Trait Anxiety Inventory Scale; 10-item Centre for Epidemiologic Studies Depression Scale: no difference between groups at baseline.
Interventions	Prerandomisation: 672 participants eligible, approached 486 (others not available for consent), declined 183; 303 enroled, 3 did not complete baseline measures **Intervention** (150 participants): deceased: 5, withdrawal: 3, completed 1 week: 135, 1 month: 130, 3 months: 126, 6 months: 117, 12 months: 116 **Control** (150 participants): deceased: 2, withdrawal: 3, completed 1 week: 132, 1 month: 135, 3 months: 126, 6 months: 126, 12 months: 123 Duration of treatment and follow-up details: 12 months, follow-up at 1 week, 1 month, 3 months, 6 months, and 12 months. Telephone follow-up: minimum 15 attempts, if no response they were sent an email.
Outcomes	**Primary outcome**

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frantatoni 2022 *(Continued)*

	• Improvement in mental health of parents (self-efficacy, stress, anxiety, and depression) **Secondary outcome** • Improvement in health outcomes during the 12 months after NICU discharge
Notes	Ethics: institutional review board approval. Declarations of interests/disclosures: none declared. Funding: Patient-Centered Outcomes Research Institute Award (IHS-1403-11567). Trial registration or protocol registration or publication: NCT02643472.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization occurred after completion of the baseline surveys, stratified by infant birth weight (>/=1500 g or <1500 g). Those in the >1500g stratum were randomized in permuted blocks of 2 or 4 with random variation of the blocking number. As fewer infants were expected in the <1500g stratum, random permuted blocks of size 2 were used." Comment: stratified, randomised.
Allocation concealment (selection bias)	Low risk	Quote: "The randomization schedule was created in Stata/SE 13.1 and implemented in the REDCap online system." Comment: automated computerised system to allocate.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "After enrollment and administration of the baseline surveys, the participant randomization determination was displayed in REDCap to the research assistant, who immediately shared it with the participant." Comment: participant and research assistant not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Efforts were made to blind principal and co-investigators during the study." Comment: no mention if investigator undertaking analysis was blinded. No mention if data collector was blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "see CONSORT diagram" Attrition rates were reported for each follow up timepoint. 34 and 27 lost to follow up in the 12 month time point for intervention and control respectively." Comment: by 12 months, high rate of loss to follow-up. Investigators reported 88% follow-up rate including all time points (higher at the start).
Selective reporting (reporting bias)	Low risk	Clinical trial registration details provided and protocol published under the same title (Carty 2018).
Baseline outcomes measurement	Low risk	Quote: "Differences in outcome measures at baseline were minor, ranging from 0.1 points to 1.2. One participant completed the baseline assessments after discharge and was excluded from baseline scale analyses (n=299)."
Baseline characteristics	Low risk	Quote: "No differences in demographic or patient characteristics were noted between randomization groups (Table 1)."

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Frantatoni 2022 *(Continued)*

Other bias	Unclear risk	Funding sources detailed. Ethics approval obtained. No mention of whether authors had any conflicts of interest.

Gorelick 2006

Study characteristics	
Methods	Study design: 3-arm, parallel group, single blind Primary study: – Allocation: 1:1:1 Controlled: standard care (control) vs intensive primary care linkage vs care co-ordinator/case management (CC/CM) Blinding: single Arms: 3
Participants	Inclusion criteria: aged 2–18 years; treated in paediatric ED visit for acute asthma; residents of Milwaukee Exclusion criteria: primary caregivers NESB (as patient information all English); other chronic pulmonary disease; tracheostomy; previous care co-ordinator or case management support Recruitment: Children's Hospital Wisconsin ED Setting: ED Location: Metropolitan Milwaukee Significant differences between groups at baseline: no **Baseline characteristics** Age (years): control: 6.4; PCL: 7.1; CC/CM: 6.8 Gender (male): control: 54.5%; PCL: 58.9%; CC/CM: 57.1% Ethnicity • Black: control: 66.7%; PCL: 22.2%; CC/CM: 8.1% • White: control: 70.5%; PCL: 23.1%; CC/CM: 5.3% • Latino: control: 70.4%; PCL: 18.5%; CC/CM: 9.8% Public insurance: control: 66.7%; PCL: 60%; CC/CM: 53.1% Chronic Severity Index • Mild intermittent: control: 28.2; PCL: 31.7; CC/CM: 31.3 • Mild persistent: control: 31.0; PCL: 24.1; CC/CM: 28.1 • Moderate persistent: control: 23.9; PCL: 27.9; CC/CM: 31.3 • Severe persistent: control: 16.9; PCL: 16.5; CC/CM: 9.4 Median ED visits in last 12 months: control: 2; PCL: 2; CC/CM: 2 Median hospitalisations in last 12 months: control: 0; PCL: 0; CC/CM: 0 Lives with smoker: control: 39.8%; PCL: 36.5%; CC/CM: 41.1%

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Gorelick 2006 *(Continued)*

	Cared for by smoker: control: 31.4%; PCL: 35.1%; CC/CM: 34.7% Used controller medication (persistent asthma only): control: 73%; PCL: 72.3%; CC/CM: 61.1%
Interventions	Prerandomisation: 352 participants **Intervention 1** (118 participants): intensive primary care linkage group = usual ED teaching/discharge care planning. Fax chart and treatment recommendations to primary care provider. Primary care provider telephone contact and contact with family **Intervention 2** (118 participants): case co-ordination/case management. Intervention 1 + up to 6 home visits by CC/CM, linkage to social services + telephone follow-up **Control** (116 participants): usual ED discharge care Duration of treatments and follow-up details: 6 months' follow-up (February 2003 to May 2004)
Outcomes	**Primary outcome** • Number of ED visits **Secondary outcomes** • Quality of life • Controlled medication use
Notes	Ethics: reviewed and approved by Children's Hospital of Wisconsin institutional review board, informed consent for participation obtained from parent/guardian. Declarations of interests/disclosures: authors declared none. Funding: Robert Wood Johnson Foundation Emergency Department Demonstration Project grant, the Allergy Research Foundation, the American Academy of Asthma, Allergy and Immunology. Trial registration or protocol registration or publication: DOI 10.1542/peds.2005-2000J.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Subjects were assigned to intervention groups by simple random allocation using a computer generated list. Group assignment was placed in a sealed, opaque envelope in a sequentially numbered study packet. After consent, each subject was enrolled using the next numbered packet."
Allocation concealment (selection bias)	Low risk	Comment: could not determine/predict 'next' allocated intervention using their method.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: participants could not be blinded to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Six months after the ED visit, follow up information was obtained from the primary caregiver by telephone survey … the person performing the telephone interviews was blinded to the subject's treatment group assignment." Comment: possible that parents could have told research assistant which group they belonged to. No mention of analysis being blinded.
Incomplete outcome data (attrition bias)	High risk	Quote: "Overall, 78% of subjects completed follow up … the 77 patients lost of follow up or excluded from the analysis were similar to those completing the

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Gorelick 2006 *(Continued)*

All outcomes		study with regard to age, chronic asthma severity and ED visits in the past 12 months. Those lost to follow up were more likely to have public insurance than those completing the study and to be non white." Comment: there was a difference between groups (lost to follow-up vs not), ethnicity, and insurance status.
Selective reporting (reporting bias)	Unclear risk	No trial registration or protocol information provided.
Baseline outcomes measurement	Unclear risk	Quote: "Fifty-five (20%) subjects were missing baseline chronic severity categorization." Comment: study did not mention if there were differences in missing information between groups.
Baseline characteristics	Low risk	Quote: "There were no important differences among the groups in clinical and demographic features."
Other bias	Low risk	Ethics: reviewed and approved by Children's Hospital of Wisconsin institutional review board, informed consent for participation obtained from parent/guardian. Declarations of interests/disclosures: authors declared no conflicts or disclosures. Funding: Robert Wood Johnson Foundation Emergency Department Demonstration Project grant, the Allergy Research Foundation, the American Academy of Asthma, Allergy and Immunology. Trial registration or protocol registration or publication: DOI 10.1542/peds.2005-2000J.

Howe 2005

Study characteristics	
Methods	Study design: randomised controlled trial Primary study: compare effects of 3 nursing interventions on glycaemic control Allocation: 1:1:1 Controlled: standard care Blinding: for analysis (not for intervention) Arms: 3; standard care (control) vs single education session vs education and telephone case management Centre: Children's Hospital Philadelphia Dates and follow-up: 1984–1993, 6-month intervention/follow-up
Participants	Inclusion criteria: aged 1–16 years; 2 × HbA1c ≥ 8.5% consecutive, diagnosed type 1 diabetes mellitus for ≥ 1 year Exclusion criteria: –

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Howe 2005 *(Continued)*

Recruitment: study co-ordinator identified potential participants by reviewing demographic and most recent HbA1c data in the diabetes database. Those ≥ 8.5% were identified and flagged. If at the next visit it was still ≥ 8.5%, the clinician approached them regarding interest in the study.

Setting: outpatient department clinic (diabetes centre)/telephone

Location: Diabetes Centre for Children

Significant differences between groups at baseline: no

Baseline characteristics

Age (years): control: 12.2 (SD 3.7); education: 13.6 (SD 2.0); education + telephone case management: 12.1 (SD 4) (P = 0.29)

Gender (male): control: 16 (39%); education: 12 (29%); education + telephone case management: 13 (32%) (P = 0.84)

Ethnicity

- White: control: 14 (34%); education: 12 (43%); education + telephone case management: 2 (33%)
- African American: control: 13 (32%); education: 7 (25%); education + telephone case management: 1 (17%)
- Other: control: 14 (34%); education: 9 (32%); education + telephone case management: 3 (50%) (P = 0.85)

Diabetes measures

- HbA1c: control: 10.2 (SD 1.4); education: 10.1 (SD 1.2); education + telephone case management: 10.0 (SD 1.4) (P = 0.88)
- Adherence: control: 51.2 (SD 25.1); education: 49.8 (SD 7.5); education + telephone case management: 48.3 (SD 19.7) (P = 0.91)
- Diabetes knowledge: control: 83.6 (SD 10); education: 81.6 (SD 12.5); education + telephone case management: 83.8 (SD 11.3) (P = 0.62)
- Parent–child teamwork: control: 61.2 (SD 21.0); education: 53.0 (SD 26.4); education + telephone case management: 55.0 (SD 28.7) (P = 0.5)

Interventions	Prerandomisation: 75 participants **Intervention 1** (21 participants): education – seen every 3 months as per control group. In addition, 1 education session with study co-ordinator (masters prep nurse who was a member of diabetes centre where study was conducted). Goal of education programme to provide families with basic diabetes management skills. Customised written guidelines provided including insulin doses for hyperglycaemia and for varying carbohydrate loads. At end of session, parent expected to identify problems and know when to call nurse practitioner for help. Children aged > 8 years asked to participate in education. **Intervention 2** (26 participants): education + telephone case management – received standard care + education as already described + weekly telephone calls for 3 months or until the 1st clinic visit then bimonthly calls from study co-ordinator. At time of enrolment, families were given an appointment 3 months after the start of study but if failed to attend/cancelled, required rescheduling which changed time frame. Study co-ordinator followed standardised telephone protocol to review blood sugar levels, safety issues related to hypoglycaemia and hyperglycaemia, problem-solving skills, diet and meal planning, and changing insulin dose. The co-ordinator also discussed parenting and behaviour management skills with parents as needed. Telephone calls lasted 5–15 minutes. The co-ordinator communicated with and collaborated with child's primary team on developments/changes in diabetes care and life issues. **Control** (28 participants): standard care: visits with nurse practitioner and endocrinologist, ideally every 3 months although time between appointments was at discretion of parent who called to schedule appointments. During the 30-minute clinic visit, HbA1c value obtained, blood glucose records re-

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Howe 2005 *(Continued)*

	viewed, problems identified, target goals determined and education provided as needed and as time permitted. Between visits, the family contacted the nurse practitioner for assistance. Co-interventions or additional treatments: none Duration of treatments and follow-up details: 6-month follow-up
Outcomes	**Primary outcome** • HbA1c **Secondary outcome** • Measures of diabetes (diabetes knowledge, adherence, and better parent/child teamwork)
Notes	Ethics: institutional review board at Children's Hospital Philadelphia-approved study. Declarations of interests/disclosures: not reported. Funding: not reported. Trial registration or protocol registration or publication: DOI: 10.1016/j.pedn.2004.12.010.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A randomisation schedule was produced using SAS program with subjects blocked by race, age group, sex and family structure (single vs two parents). Within each block, subjects were randomly assigned to one of three treatment groups." Comment: unclear how participants were 'blocked'.
Allocation concealment (selection bias)	Unclear risk	Comment: as participants were 'blocked' under groups, potentially allocation could have been predicted if the previous allocation was known.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: participants could not be blinded to intervention. Not possible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no mention of who performed analysis and whether they were blind to allocation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "we estimated a total of 135 subjects (45 per group) were needed, assuming an overall type 1 error of 0.05 and power of 85%. Although the original goal was to have 135, after 3 years of subject recruitment, the team closed the study at 75 subjects." Comment: study numbers not sufficient.
Selective reporting (reporting bias)	Unclear risk	No trial registration information or previous protocol information was provided.
Baseline outcomes measurement	Low risk	Quote: "At baseline, the mean HbA1c for all study participants was 10.2 F 1.4%. There were no significant differences among groups at baseline for HbA1c, ADH [adherence], TEAM [parent–child teamwork], or KNOW [diabetes knowledge]. Table 1 displays baseline data for the three groups."

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Howe 2005 *(Continued)*

Baseline characteristics	Low risk	Quote: "Table 1 displays baseline data for the three groups." Comment: no significant ethnic or age differences between study groups at baseline.
Other bias	Unclear risk	Ethics: institutional review board at Children's Hospital Philadelphia-approved study. Declarations of interests/disclosures: not reported. Funding: not reported. Trial registration or protocol registration or publication: DOI: 10.1016/j.pedn.2004.12.010.

Karnick 2007

Study characteristics	
Methods	Study design: sequential randomised trial, parallel Allocation: 1:1:1 Controlled: asthma education (group 1) Blinding: not reported Arms: reinforced education (group 2), case management (group 3) Centre: Mount Sinai Hospital Dates and follow-up: recruitment July 2000 to May 2001, retrospective data 1 year, follow-up 9 months
Participants	Inclusion criteria: aged 1–16 years with asthma Exclusion criteria: comorbidities Recruitment: from Mount Sinai Hospital's ED, inpatient units, and patients referred to Sinai's pulmonology clinic **Baseline characteristics**: all not significantly different at baseline EXCEPT number of unscheduled clinic visits for group 3 (case management) in the year prior to intervention Male: education: 55%; reinforced education: 66%; case management: 59% Female: education: 45%; reinforced education: 34%; case management: 41% Ethnicity • Non-Hispanic black: education: 70%; reinforced education: 65%; case management: 64% • Hispanic education: 30%; reinforced education: 35%; case management: 34% • Other education: 0%; reinforced education: 0%; case management: 1% Age mean (years) education: 5.54; reinforced education: 5.13; case management: 5.71 Insurance • None: education: 3%; reinforced education: 0%; case management: 0% • Medicaid: education: 86%; reinforced education: 90%; case management: 91% • Private: education: 11%; reinforced education: 10%; case management: 9%

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Karnick 2007 *(Continued)*

	Symptoms • Daily: education: 0%; reinforced education: 0%; case management: 3% • 2–6 times per week: education: 80%; reinforced education: 82%; case management: 79% • < once per week: education: 20%; reinforced education: 18%; case management: 19% Albuterol (rescue medication) • Daily: education: 9; reinforced education: 10; case management: 14 • 2–6 times per week: education: 45; reinforced education: 46; case management: 44 • Once per week: education: 32; reinforced education: 24; case management: 17 • < once per week/rarely: education: 14; reinforced education: 21; case management: 24 Healthcare utilisation (1 year before intervention) • ED visits (mean): education: 1.87; reinforced education: 1.62; case management: 2.1 • Hospitalisations (mean): education: 1.01; reinforced education: 1.03; case management: 1.07 • Hospital days (mean): education: 2.11; reinforced education: 2.04; case management: 2.53 • Unscheduled clinic visits (mean): education: 2.53; reinforced education: 2.53; case management: 3.46 ($P < 0.05$) School days missed (mean): education: 6.65; reinforced education: 5.38; case management: 6.62
Interventions	Prerandomisation: 212 participants; no mention of eligible participants **Intervention 1** (74 participants): 20- to 30-minute education session and the use of asthma treatment plan – referred back to primary care provider **Intervention 2** (68 participants): reinforced asthma education monthly, encouraged to contact asthma educator **Intervention 3** (70 participants): reinforced education and case management – initial case management evaluation, identify problems and needs and to devise a solution action plan, support the family in carrying out the plan **Control** (all groups were control of their group): self-control Duration of treatment and follow-up details: 9 months. Follow-up retrospective 1 year, prospective 9 months
Outcomes	**Primary outcomes** • Hospitalisation • Hospital days • ED visits • Clinic visits **Secondary outcomes**: none
Notes	Ethics: institutional review board approval obtained. Declarations of interests/disclosures: – Funding: Michael Reese Health Trust and the Crown Foundation. Trial registration or protocol registration or publication: DOI: 10.1080/02770900601125391.

Risk of bias

Bias	Authors' judgement	Support for judgement

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Karnick 2007 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Comment: no mention of randomisation method.
Allocation concealment (selection bias)	Unclear risk	Comment: no mention of concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: blinding of participants not possible to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no mention of how data analysis was performed (blinding, etc.).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "there were 212 participants who agreed to take part in the study, and of these 165 (77.8%) completed the 9-month follow up. Participants were considered lost to follow up after repeated attempts to contact them using various means (telephone, written communication, etc.) were unsuccessful for three consecutive months." "We extrapolated follow up data to one year's time to make it comparable to baseline data." Comment: group 1 had 55/74, group 2 had 54/68, and group 3 had 56/70 complete the follow-up. No mention of significant difference in attrition rates, or reasons for lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Mention of an oral abstract presentation at 130th meeting of American Public Health Association, 2002 (Abstract 41651).
Baseline outcomes measurement	Unclear risk	Quote: "The baseline characteristics of participants in each group are displayed in Table 1. There were no significant differences among the groups with the exception of the number of unscheduled clinic visits in the baseline year." Comment: the difference was a higher number of unscheduled clinic visits at baseline for the intervention group (group 3). Hospitalisation and ED presentation rates were similar. This may introduce a bias in favour of the intervention. The analysis found no difference in rate of hospitalisation, ED attendance, but did find a difference in unscheduled clinic visits, which was not included in the outcomes of interest in this systematic review. The effect of the decrease in unscheduled clinic visits may have led to an unpredictable risk of bias for hospitalisation and ED presentations.
Baseline characteristics	Low risk	Quote: "The baseline characteristics of participants in each group are displayed in Table 1. There were no significant differences among the groups with the exception of the number of unscheduled clinic visits in the baseline year."
Other bias	High risk	Funding sources declared. However, study had to shorten the follow-up period to 9 months (instead of 12) and thus extrapolated data to make outcomes of 12 months. Quote: "Funding constraints limited the amount of time that we were able to follow enrolled participants for 9 months … we needed to extrapolate 12 months of data from 9 months …" Ethics: institutional review board approval obtained. Declarations of interests/disclosures: not reported. Funding: Michael Reese Health Trust and the Crown Foundation. Trial registration or protocol registration or publication:

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Karnick 2007 *(Continued)*

DOI: 10.1080/02770900601125391.

Katz 2014

Study characteristics	
Methods	Study design: randomised controlled trial, parallel Primary study: – Allocation: 1:1:1 Controlled: active comparator Blinding: due to the nature of intervention, unable to blind participants. Study data collection was not blinded. No mention of subgroup analysis being blinded Arms: 3 arms; standard care vs care ambassador vs care ambassador+psychoeducation Centre: single centre (assumed not mentioned) Dates and follow-up: recruitment over 4-month period, follow-up 2 years
Participants	Inclusion criteria: aged 8–16 years; type 1 diabetes mellitus duration ≥ 6 months; established care at centre (> 3 visits in past 2 years, or > 2 visits in 1 year if diabetes duration was < 1 year) Exclusion criteria: major psychiatric illness; neurocognitive disability; another significant medical condition; unstable living environment (defined by department of social services or department of youth services involvement) Recruitment: of 174 people, 154 (89%) agreed to participate. 20 did not; 16 had lack of time or interest, 2 had family problems, 1 had concerns regarding privacy, 1 anticipated moving **Baseline characteristics** Recruitment: control: 51; care ambassador: 52; care ambassador+psychoeducation: 50 Age (years): control: 12.5 (SD 2.3); care ambassador: 13.4 (SD 2.4); care ambassador+psychoeducation: 12.7 (SD 2.2) Gender: (female): control: 45%; care ambassador: 65%; care ambassador+psychoeducation: 58% Ethnicity: non-white: control: 2%; care ambassador: 15%; care ambassador+psychoeducation: 10% Body mass index (Z score standard deviation score): control: 0.6 (SD 0.8); care ambassador: 0.9 (SD 0.7); care ambassador+psychoeducation: 0.8 (SD 0.7) HbA1c > 8%: control: 55%; care ambassador: 58%; care ambassador+psychoeducation: 52% Diabetes duration (years): control: 5.7 (SD 3.5); care ambassador: 6.8 (SD 3.2); care ambassador+psychoeducation: 6.5 (SD 3.8) Highest parental education • High school or less: control: 14%; care ambassador: 15%; care ambassador+psychoeducation: 6% • Some college: control: 18%; care ambassador: 17%; care ambassador+psychoeducation: 30% • College or more: control: 69%; care ambassador: 67%; care ambassador+psychoeducation: 64% Significant differences between groups at baseline: yes for sex and ethnicity
Interventions	Prerandomisation: 174 participants; 20 declined, 1 had maturity-onset diabetes mellitus and was excluded

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Katz 2014 *(Continued)*

	Intervention 1 (52 participants): monthly telephonic outreach by care ambassador, in addition to the basic 3 quarterly visits **Intervention 2** (50 participants): usual 3-monthly visits by care ambassador, monthly phone calls/ emails, psychoeducational intervention at 3 monthly visits **Control** (51 participants): standard care: usual 3-monthly visits, monthly telephone calls/emails Co-interventions or additional treatments: none Duration of treatment and follow-up details: 2 years, surveys at baseline, 1 year and 2 years
Outcomes	**Primary outcome** • HbA1c at 2 years **Secondary outcomes** • Maintaining parent involvement (Diabetes Family Responsibility Questionnaire, Diabetes Family Conflict Scale, Paediatric Quality of Life Inventory) • Avoiding deterioration in glycaemic control
Notes	Ethics: institutional review board approved the study protocol and parents/youth provided written informed consent/assent before beginning any study procedures. Declarations of interests/disclosures: none declared. Funding: Charles H Hood Foundation, Katherine Adler Astrove Youth Education Fund, the Maria Griffin Drury Pediatric Fund, the Eleanor Cheterman Beatson Fund, NIH T32 DK 7260-35 to the Joslin Diabetes Center; Health Resources and Services Administration grant T32 HP10018 to the Harvard Pediatric Health Services Research Fellowship Program, K12 DK094721-02 to the Joslin Diabetes Centre/Children's Hospital Boston and grant P30DK036836 to the Diabetes and Endocrinology Research Center. Trial registration or protocol registration or publication: DOI: 10.1111/pedi.12065.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomized in two strata according to age (8–12 or >=13 yr) to one of three groups …" Comment: no mention of how the sequence generation was done.
Allocation concealment (selection bias)	Unclear risk	No mention of this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants could not be blinded to this type of intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention if outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "Three families completed only the initial survey assessment and their data was excluded from the analysis of the survey results. Three families completed only baseline and 1 yr [year] survey data and their 1 yr survey data were carried forward in the analysis."

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Katz 2014 *(Continued)*

		Comment: no mention as to which arms the 6 families belonged to. Numbers were low, 4% attrition rate (only for survey portion).
Selective reporting (reporting bias)	Unclear risk	No trial protocol information or trial number registration provided.
Baseline outcomes measurement	Low risk	Quote: "The three groups were comparable with regard to age, diabetes duration, proportion on insulin pump, frequency of blood glucose monitoring, A1c, pubertal stage, parental involvement in diabetes management, parent- and child-report of diabetes-specific family conflict, and parent proxy-report and child self-report of youth QOL [quality of life] at baseline (Table 2). There were statistically significant differences in sex and race/ethnicity between the SC [standard care] and CA+ [care ambassador and psychoeducation] groups, suggesting the need to adjust for these in the multivariate analyses."
Baseline characteristics	Low risk	Quote: "The three groups were comparable with regard to age, diabetes duration, proportion on insulin pump, frequency of blood glucose monitoring, A1c, pubertal stage, parental involvement in diabetes management, parent- and child-report of diabetes-specific family conflict, and parent proxy-report and child self-report of youth QOL [quality of life] at baseline (Table 2). There were statistically significant differences in sex and race/ethnicity between the SC [standard care] and CA+ [care ambassador and psychoeducation] groups, suggesting the need to adjust for these in the multivariate analyses."
Other bias	Low risk	Ethics: the institutional review board approved the study protocol and parents/youth provided written informed consent/assent before beginning any study procedures. Declarations of interests/disclosures: no conflicts of interest declared. Funding: Charles H Hood Foundation, Katherine Adler Astrove Youth Education Fund, the Maria Griffin Drury Pediatric Fund, the Eleanor Cheterman Beatson Fund, NIH T32 DK 7260-35 to the Joslin Diabetes Center; Health Resources and Services Administration grant T32 HP10018 to the Harvard Pediatric Health Services Research Fellowship Program, K12 DK094721-02 to the Joslin Diabetes Center/Children's Hospital Boston and grant P30DK036836 to the Diabetes and Endocrinology Research Center. Trial registration or protocol registration or publication: 10.1111/pedi.12065.

Laffel 1998

Study characteristics	
Methods	Study design: parallel randomised controlled trial Allocation: 1:1 Controlled: standard care group Blinding: not possible to intervention Arms: 2: standard care vs care ambassador Centre: Paediatric and Adolescent Unit of Joslin Diabetes Centre Dates and follow-up: no dates for study recruitment/completion, but participants in both groups followed for 24 months maximum (or until they 'dropped out')

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Laffel 1998 *(Continued)*

Participants	Inclusion criteria: aged 10–15 years with > 1 year of insulin-dependent diabetes mellitus receiving care at Joslin Diabetes Centre; daily insulin requirement of > 0.5 U/kg, HbA1c 6.6–10.4%; no other serious medical or psychological issues; live in New England or New York and ≥ 1 outpatient department visit in 1992–1993 Exclusion criteria: families planning to change site of child's care (e.g. due to relocation or health insurance reason) Setting: Paediatric and Adolescent unit of Joslin Diabetes Centre Location: outpatient department Significant differences between groups at baseline: none **Baseline characteristics** Age (years): care ambassador: 12.7 (SD 1.38); standard care: 12.9 (SD 1.42) Gender (male): care ambassador: 49%; standard care: 41% Duration of diabetes (years): care ambassador: 5.6 (SD 2.6); standard care: 6.0 (SD 3.2) Age at diabetes diagnosis (years): care ambassador: 7.1 (SD 2.7); standard care: 6.9 (SD 3.2) HbA1c at entry: care ambassador: 8.6% (SD 1.1%); standard care: 8.7% (SD 1.2%)
Interventions	Prerandomisation: 171 participants **Intervention** (89 participants): care ambassador designed to help patients and their families receive ambulatory diabetes care as prescribed by the patient's usual diabetes team. Assisted families with their appointments and scheduling, helped with questions about billing or insurance by directing them to appropriate personnel. The primary task of the care ambassador was to monitor clinic attendance of intervention participants and to provide telephone or written outreach to families after missed or cancelled appointments. Not medically trained (college graduates) and encouraged patients and families to seek medical advice from their own healthcare team in a timely manner. **Control** (82 participants): standard care consisting of quarterly visits with multidisciplinary diabetes team
Outcomes	**Primary outcomes** • Frequency of medical visits • HbA1c **Secondary outcomes** • Risk of severe hypoglycaemia • Risk of hospitalisation and ED use
Notes	Ethics: approved by Joslin Committee on Human Studies and written informed consent was obtained from families in the care ambassador intervention group. Declarations of interests/disclosures: not reported. Funding: National Institute of Health (grant DK-46887) and the Charles H. Hood Foundation. Trial registration or protocol registration or publication: DOI: 10.1097/00019514-199806040-00006.

Risk of bias

Bias	Authors' judgement	Support for judgement

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Laffel 1998 *(Continued)*

Random sequence generation (selection bias)	High risk	No information provided.
Allocation concealment (selection bias)	High risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants could not be blinded to this type of intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	Sporadic baseline data for 30% of participants with no justification why this data were not available. Differing follow-up time frames for control and intervention groups (2028 for intervention, 1282 months for control group).
Selective reporting (reporting bias)	Unclear risk	No mention of trial registration or a priori published protocol.
Baseline outcomes measurement	Low risk	Quote: "There were no significant differences in the baseline characteristics between the care ambassador intervention (N=89) and standard care (N=82) groups with respect to age, gender distribution, duration of IDDM, age at diagnosis, glycaemic control, state of residency or frequency of medical visits during the preceding year (see Table 1)."
Baseline characteristics	Low risk	Quote: "There were no significant differences in the baseline characteristics between the care ambassador intervention (N=89) and standard care (N=82) groups with respect to age, gender distribution, duration of IDDM, age at diagnosis, glycaemic control, state of residency or frequency of medical visits during the preceding year (see Table 1)."
Other bias	Unclear risk	Ethics: approved by Joslin Committee on Human Studies and written informed consent was obtained from families in the care ambassador intervention group. Declarations of interests/disclosures: not reported. Funding: National Institute of Health (grant DK-46887) and the Charles H. Hood Foundation. Trial registration or protocol registration or publication: –

Looman 2015

Study characteristics	
Methods	Study design: randomised controlled trial Primary study: Looman 2015 Allocation: 1:1:1 Controlled: usual care Blinding: –

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Looman 2015 *(Continued)*

	Arms: advanced practice registered nurse telephone-based care co-ordination intervention vs advanced practice registered nurse telephone + video-based care co-ordination intervention Centre: Minnesota Dates and follow-up: 2010, 30 months' follow-up, concluded data collection mid-2014
Participants	Inclusion criteria: children aged 2–15 years who experience ≥ 1 of 5 common health consequences due to a health condition lasting ≥ 12 months. ≥ 4/5 criteria based on Child and Adolescent Health Measurement Initiative needed to be met by the child. Children had to be part of the special needs clinic Exclusion criteria: non-English speaking people Recruitment: 150 target sample size determined based on a power analysis Significant differences between groups at baseline: no for predisposing factors, need factors or enabling factor. No differences in the dependent variables. 1 variable, the number of complex chronic conditions was significantly associated with satisfaction scores on 1 measure at baseline for the total sample. On the provider communication items, "listened carefully to me" and "spent enough time with the child" were significantly higher for children with multiple complex chronic conditions versus a single complex chronic conditions. **Baseline characteristics** Male: control: 27 (57%); telephone: 29 (58%); telephone+video: 24 (47%) Age (years): • 2–5: control: 21 (45%); telephone: 22 (44%); telephone+video: 23 (45%) • 6–12: control: 19 (40%); telephone: 22 (44%); telephone+video: 20 (39%) • 13–15: control: 7 (15%); telephone: 6 (12%); telephone+video: 8 (16%) Primary insurance • Private: control: 28 (60%); telephone: 27 (54%); telephone+video: 22 (43%) • Public: control: 18 (38%); telephone: 23 (46%); telephone+video: 29 (57%) • Uninsured: control: 1 (2%); telephone: 0 (0%); telephone+video: 0 (0%) Neurological impairment: control: 40 (85%); telephone: 43 (86%); telephone+video: 41 (80%) Number with single complex chronic conditions: control: 7 (15%); telephone: 7 (14%); telephone+video: 7 (14%) Technology assistance: control: 23 (49%); telephone: 21 (42%); telephone+video: 26 (51%) Race • White: control: 29 (62%); telephone: 32 (64%); telephone+video: 33 (65%) • Black: control: 2 (4%); telephone: 8 (16%); telephone+video: 10 (20%) • Asian: control: 4 (9%); telephone: 1 (2%); telephone+video: 3 (6%) • Multiracial: control: 1 (2%); telephone: 8 (16%); telephone+video: 4 (8%) Missing: control: 11 (23%); telephone: 1 (2%); telephone+video: 1 (2%) **Caregiver characteristics** Relationship to child • Mother: control: 28 (60%); telephone: 41 (82%); telephone+video: 40 (78%) • Father: control: 2 (4%); telephone: 2 (4%); telephone+video: 3 (6%) • Other: control: 6 (13%); telephone: 6 (12%); telephone+video: 7 (14%) Missing: control: 11 (23%); telephone: 1 (2%); telephone+video: 1 (2%)

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Looman 2015 *(Continued)*

	Age (years) • 18–34: control: 16 (34%); telephone: 22 (44%); telephone+video: 15 (29%) • 35–54: control: 20 (43%); telephone: 25 (50%); telephone+video: 33 (65%) • 55–64: control: 0 (0%); telephone: 2 (4%); telephone+video: 2 (4%) Missing: control: 11 (23%); telephone: 1 (3%); telephone+video: 1 (2%) Annual household income • < USD 22,000: control: 5 (11%); telephone: 12 (24%); telephone+video: 18 (35%) • USD 22,001–50,000: control: 15 (32%); telephone: 18 (33%); telephone+video: 22 (43%) • USD 50,000–88,000: control: 6 (13%); telephone: 11 (22%); telephone+video: 4 (8%) • > USD 88,000: control: 10 (21%); telephone: 7 (14%); telephone+video: 6 (12%) Missing: control: 11 (23%); telephone: 2 (4%); telephone+video: 1 (2%) Level of education • High school/GED: control: 2 (4%); telephone: 10 (20%); telephone+video: 9 (19%) • Some college/2 years of college: control: 16 (34%); telephone: 22 (44%); telephone+video: 22 (43%) • 4 years of college: control: 8 (17%); telephone: 9 (18%); telephone+video: 7 (14%) • > 4 years of college: control: 9 (19%); telephone: 1 (2%); telephone+video: 6 (12%) Missing: control: 12 (26%); telephone: 8 (16%); telephone+video: 7 (14%)
Interventions	Prerandomisation: screened and included, 172 consented, 9 withdrew prior to randomisation, 163 remaining for randomisation **Intervention 1** (54 participants): telephone-based care co-ordination intervention **Intervention 2** (54 participants): telephone + interactive video-based care co-ordination intervention **Control** (55 participants): usual care Co-interventions or additional treatments: – Duration of treatments and follow-up details: 30 months' follow-up
Outcomes	**Primary outcomes** • Primary caregiver's satisfaction with healthcare services and perceived adequacy at year 1 and year 2 • Paediatric Quality of Life Inventory **Secondary outcomes** • Functional status II(R) measure • Planned visits • Unplanned visits
Notes	Ethics: Human Research Protection Program at the University of Minnesota on 12 October 2009, renewed during all active phases of the trial (IRB 0908M70627). Declarations of interests/disclosures: no conflicts of interest. Funding: National Institute of Nursing Research, National Institutes of Health grant R01 NR010883. Trial registration or protocol registration or publication: – Additional: we contacted the corresponding author for this research group to obtain raw data for ED presentations vs hospitalisations (originally presented as a combined statistic in the manuscript). The author kindly provided us with the raw data.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Looman 2015 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "subjects were randomly assigned to one of the three study groups …" Comment: no description of the randomisation technique given.
Allocation concealment (selection bias)	Unclear risk	Comment: no description given of allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: no description given of blinding of participants. Given the nature of the intervention, likely that participants were unblinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Data was collected using a mailed survey to the primary family caregiver at three time points." Comment: no description given of blinding to outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "of 375 eligible screened, 172 consented and enrolled. 9 subjects withdrew prior to randomisation, 19 late surveys excluded from analysis (9C 7T 3V), 7 subjects withdrew in year 1, 12 late surveys excluded from analysis at year 1 (3C 6T 3V), 8 subjects withdrew in year 2, 2 late surveys excluded from analysis (2T)." Comment: < 50% of eligible families consented to the study. 148 participants completed year 2, which is 2 lower than the target 150 for power calculation.
Selective reporting (reporting bias)	Unclear risk	No trial registration or protocol information provided.
Baseline outcomes measurement	Low risk	Quote: "Child physical quality of life scores in the video group (mean [M] = 39.9, SD = 29.2) were lower than those in the telephone group (M = 56.5, SD = 31.6) and the control group (M = 54.0, SD = 27.6), and this difference approached significance (p = .059). All other mean baseline subscale scores for parent, family, and child quality of life were not significantly different by intervention group."
Baseline characteristics	Unclear risk	Quote: "The proportion of parents with a college education in the control group (57%) was significantly higher than the proportion of parents with a college education in the intervention groups (29%; v2 = 5.7, df = 1, p = .017). The proportion of single parents in the control group (17%) was smaller than in the intervention groups (39%), and this difference approached significance (v2 = 3.7, df = 1, p = .055). There were no other significant differences between groups at baseline on child demographic or condition characteristics based on chi-square tests." Comment: the study did not address how they adjusted the outcomes but did mention it as a possible source of bias in the discussion. Bias would be towards null.
Other bias	Low risk	Ethics: Human Research Protection Program at the University of Minnesota on 12 October 2009, renewed during all active phases of the trial (IRB 0908M70627). Declarations of interests/disclosures: no conflicts of interest to declare.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Looman 2015 *(Continued)*

	Funding: National Institute of Nursing Research, National Institutes of Health grant R01 NR010883. Trial registration or protocol registration or publication: –

Parikh 2021

Study characteristics	
Methods	Study design: pilot prospective randomised controlled trial Allocation: 1:1 Controlled: yes (with standard care) Blinding: no, not by intervention Arms: 2 Centre: single tertiary paediatric hospital, Washington District of Columbia Dates and follow-up: enrolment between September and December 2018, then followed for 6 months
Participants	Inclusion criteria: aged 5–12 years; enrolment in kindergarten to 8th grade at District of Columbia public school; hospitalisation with primary diagnosis of exacerbation of asthma; coverage with public (Medicaid) insurance; discharge with a prescription for inhaled corticosteroid medication by the inpatient medical team Exclusion criteria: chronic disease other than asthma, including but not limited to serious cardiorespiratory disorder, sickle cell disease, or seizure disorder; non-English speaking; patient already enroled in an asthma study Recruitment: during inpatient hospital admission Setting: outpatient Location: Washington, District of Columbia Significant differences between groups at baseline: yes – different in median age (6 years in intervention group vs 8.5 years in control group), asthma classification and asthma control. **Baseline characteristics** Age[a] (median, years): intervention: 6 (IQR 5.0–7.5); control: 8.5 (IQR 6.5–10) Female (number): intervention: 9 (56%); control: 7 (44%) Race (number) • White: intervention: 0 (0%); control: 0 (0%) • Black: intervention: 14 (87.5%); control: 14 (87.5%) • Other: intervention: 2 (12.5%); control: 2 (12.5%) • Hispanic: intervention: 1 (6.25%); control: 2 (12.5%) Body mass index: intervention: 17.7 (IQR 15.1–24.0); control: 18.8 (IQR 15.8–24.5) Length of stay, median (days): intervention: 2 (IQR 1–2); control: 2 (IQR 1–2) Asthma classification[a] (number) • Intermittent: intervention: 1 (6.25%); control: 0 (0%)

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Parikh 2021 *(Continued)*

- Mild persistent: intervention: 5 (31.25%); control: 11 (68.75%)
- Moderate persistent: intervention: 6 (37.5%); control: 2 (12.5%)
- Severe persistent: intervention: 4 (25%); control: 3 (18.75%)

Asthma control[a] (number)

- Well controlled: intervention: 3 (18.75%); control: 6 (37.5%)
- Not well controlled: intervention: 12 (75%); control: 10 (62.5%)

[a]Important differences at baseline between intervention and control groups

Interventions	**Intervention** (16 participants): participants were exposed to 5 main study interventions. The participant-centred components included: medications in-hand at the time of discharge, primary care provider communication, patient navigator support for 6 months after discharge, school-based asthma therapy, and referral to a home visit programme to address home-based asthma triggers. Patient navigator contact at 3 days, 14 days, 1 month, 2 months, 3 months, 4 months, 5 months, and 6 months. **Control** (16 participants): both groups received asthma management plans at hospital discharge consistent with the guidelines of the National Heart, Lung, Blood Institute, including referral to an asthma speciality clinic at Children's National Hospital. In addition, participants in the control group were offered the medications in-hand at the time of discharge, and communication with the primary care provider was initiated by the primary inpatient team. Participants did not have ongoing contact with the patient navigator, school-based asthma therapy, or referral to the home visit programme initiated during the hospitalisation. Co-interventions or additional treatments: approach combined navigation support during the hospital to home transition to support aspects of care co-ordination, specifically ensuring discharge with medications in-hand, communicating with primary care providers, partnering with schools and referring to a community-based home remediation programmes to improve asthma care after hospitalisation. Duration of treatments and follow-up details: 6 months
Outcomes	**Primary outcome** • Study acceptability by caregivers (short survey at 6 months) **Secondary outcomes** • Healthcare utilisation • ED presentations at 3 months and 6 months postdischarge • Asthma morbidity – symptom-free days in the 14 days pre-interview • Caregiver quality of life assessed using Paediatric Asthma Caregiver Quality of Life Questionnaire.
Notes	Note given this was a pilot trial, unable to power secondary outcomes.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: enroled dyads were randomised using a 4-block system generated by the RedCap web-based data collection tool. This was done to account for seasonal variation during the 3-month study enrolment period. Since DC public schools are in session from September to June, study enrolment was limited to September to December to allow for co-ordination with the schools as well a 6-month follow-up while the student was still in school.
Allocation concealment (selection bias)	Low risk	Comment: enroled dyads were randomised using a 4-block system generated by the RedCap web-based data collection tool.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Parikh 2021 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Unable to blind participants to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded research assistants conducted structured follow-up interviews 3 and 6 months after enrolment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of attrition if any.
Selective reporting (reporting bias)	Unclear risk	Could not determine if there was a trial protocol published. No NCT number found (Washington DC study).
Baseline outcomes measurement	Unclear risk	Quote: "The groups did not differ in sex, race, body mass index, or hospital length of stay, but were different in age (median age 6 years in intervention vs 8.5 years in usual care group), asthma classification, and asthma control."
Baseline characteristics	Unclear risk	Quote: "The groups did not differ in sex, race, body mass index, or hospital length of stay, but were different in age (median age 6 years in intervention vs 8.5 years in usual care group), asthma classification, and asthma control." Comment: no comment made of statistical analysis to address the discrepancy, although we know this study was not powered to detect change.
Other bias	Low risk	Declaration of interest: other authors had no conflicts of interest to disclose. Financial disclosure statement: Dr Teach has received funding from NIH and Uptodate. Dr Parikh was supported by grant number K08HS024554 from the Agency for Healthcare Research and Quality. The remaining authors had no financial relationships relevant to this article to disclose. Ethics: the Children's National Hospital Institutional Review Board approved this study.

Seid 2010

Study characteristics	
Methods	Study design: randomised controlled trial Primary study: – Allocation: 1:1:1 Controlled: standard care Blinding: not to intervention Arms: standard care vs care co-ordination vs care co-ordination + problem-solving skill training Centre: San Diego, California from Federally Qualified Health Centers (subsidised community clinics, underinsured or uninsured, low income), commercial house of multiple occupancy, school/daycare, local asthma initiatives, self-referred

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Seid 2010 *(Continued)*

	Dates and follow-up: recruitment between 11 June 2004 and 15 January 2007. Final follow-up completed on 16 October 2007
Participants	Inclusion criteria: aged 2–14 years; persistent asthma diagnosis; parents who spoke English or Spanish Exclusion criteria: comorbidities, e.g. Down's syndrome Recruitment: 212 Federally Qualified Health Centers (subsidised community clinics, underinsured or uninsured, low income), commercial house of multiple occupancy 15, school/daycare 11, local asthma initiatives 3, self-referred 11 **Baseline characteristics** Age mean (years): all: 7.37 (SD 3.07); standard care: 7.26 (SD 3.02); care co-ordination: 7.47 (SD 3.13); care co-ordination+problem-solving: 7.37 (SD 3.10); P = 0.911 Gender males (number): all: 61 (54%); standard care: 61 (53%); care co-ordination: 69 (56%); care co-ordination+problem-solving: 54 (45%); P = 0.122 Ethnicity (number) • Hispanic: all: 83; standard care: 81 (70%); care co-ordination: 86 (70%); care co-ordination+problem-solving: 83 (70%); P = 0.668 • Non-Hispanic white: all: 4 (11%); standard care: 6 (5%); care co-ordination: 3 (2%); care co-ordination+problem-solving: 5 (4%) • Non-Hispanic Black: all: 8 (21%); standard care: 10 (9%); care co-ordination: 5 (4%); care co-ordination+problem-solving: 10 (8%) • Other: all: 4 (10%); standard care: 3 (3%); care co-ordination: 6 (5%); care co-ordination+problem-solving: 2 (2%) Language (number): P = 0.26 • English bilingual: all: 8 (20%); standard care: 6 (5%); care co-ordination: 14 (11%); care co-ordination+problem-solving: 5 (4%) • Spanish bilingual: all: 21 (52%); standard care: 21 (18%); care co-ordination: 24 (19%); care co-ordination+problem-solving: 18 (15%) • English non-bilingual: 15 (38%); standard care: 18 (16%); care co-ordination: 12 (10%); care co-ordination+problem-solving: 14 (12%) • Spanish non-bilingual: all: 56; standard care: 55 (48%); care co-ordination: 51 (41%); care co-ordination+problem-solving: 63 (53%) Mother's educational level (number): P = 0.411 • < 6th grade: all: 26 (65%); standard care: 23 (20%); care co-ordination: 27 (21%); care co-ordination+problem-solving: 29 (24%) • 7–9th grade: all: 25 (52%); standard care: 26 (17%); care co-ordination: 25 (17%); care co-ordination+problem-solving: 25 (18%) • 10–12th grade: all: 21 (43%); standard care: 20 (13%); care co-ordination: 20 (14%); care co-ordination+problem-solving: 22 (16%) • High school graduate: all: 8 (17%); standard care: 12 (8%); care co-ordination: 9 (6%); care co-ordination+problem-solving: 4 (3%) • Some college: all: 7 (14%); standard care: 11 (7%); care co-ordination: 7 (5%); care co-ordination+problem-solving: 3 (2%) • College graduate: all: 7 (14%); standard care: 11 (7%); care co-ordination: 7 (5%); care co-ordination+problem-solving: 3 (2%) • Graduation/professional degree: all: 1 (1%); standard care: 2 (1%); care co-ordination: 0 (0%); care co-ordination+problem-solving: 0 (0%) Asthma severity (number): P = 0.566

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Seid 2010 *(Continued)*

- Mild: all: 27 (23%); standard care: 25.3 (22%); care co-ordination: 28 (23%); care co-ordination+problem-solving: 27 (23%)
- Moderate: all: 41 (34%); standard care: 44 (38%); care co-ordination: 33 (27%); care co-ordination+problem-solving: 44 (38%)
- Severe: all: 33 (40%); standard care: 31 (28%); care co-ordination: 38 (31%); care co-ordination+problem-solving: 29 (23%)

Interventions	Prerandomisation: 610 participants: 358 excluded; did not meet eligibility 148 for age, out of area, intermittent asthma, language, already enroled, parent reports no asthma, other, Down's syndrome, homeless, refused to participate; unable to locate 118 **Intervention 1** (81 participants): in-home asthma education and care co-ordination **Intervention 2** (84 participants): in-home asthma education and care co-ordination and 6 weekly sessions of problem-solving skill training **Control** (87 participants): standard care Duration of treatments and follow-up details: follow-up at 3 months after baseline and 9 months after baseline
Outcomes	**Primary outcome** • Parent-reported child generic health-related quality of life (Paediatric Quality of Life Inventory) **Secondary outcomes** • Asthma symptoms (asthma-specific health-related quality of life) • Asthma symptom frequency (number of days and nights with asthma symptoms over 2 weeks) • Utilisation of ED, inpatient or urgent doctor's appointments for asthma over 6 months at baseline, 3 months, and 9 months
Notes	Ethics: approved by the Institutional Review Boards at Rady Children's Hospital, the RAND Corporation, and Cincinnati Children's Hospital Medical Center. Declarations of interests/disclosures: Dr Varni holds the copyright and the trademark for Paediatric Quality of Life Inventory and receives financial compensation from the Mapi Research Trust, which is a non-profit research institute that charges distribution fees to for-profit companies that use the Paediatric Quality of Life Inventory. Funding: grant from the Maternal and Child Health Bureau of the Health Resources and Services Administration (R40 MC01214/08044). The funder had no role in the design or conduct of the study; in the collection, analysis, or interpretation of the data; or in the preparation, review, or approval of the manuscript. Trial registration or protocol registration or publication: NCT00250588

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "blocked randomisation, stratified by site of care (FQHC [Federally Qualified Health Center] versus other) and disease severity (mild/mod/severe)."
Allocation concealment (selection bias)	Low risk	Quote: "prepared randomisation list were created by statistician and concealed until intervention assignment. A paediatrician with asthma expertise verified eligibility prior to assignment and the project manager carried out the assignment."

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Seid 2010 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: no mention of blinding of participants or intervention providers. Given nature of intervention, likely non-blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Bilingual bicultural research staff, blinded to the intervention group, administered surveys in English or Spanish in participants' homes. When in-person measurement was not possible, the surveys were completed by telephone or by mail. Blinding success was demonstrated by the fact that measurement staff guessed the subject's group correctly at follow up only 43% of the time – only slightly better than chance."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "see figure 1. Flow of participants." Standard care: 87, T2 complete 73, T3 complete 66, analysed 74. Care co-ordination: 81, received 78, T2 complete 71, T3 complete 65, analysed 72. Care co-ordination and problem-solving: 84, received 78, T2 complete 60, T3 complete 57, analysed 65. For Paediatric Quality of Life Inventory 59 standard care, 54 care co-ordination, and 52 care co-ordination and problem-solving. Sample size estimated 107 participants per group to achieve clinically important difference in Paediatric Quality of Life Inventory score 4.5 at 80% power (alpha 0.05, 2-sided) and 20% attrition.
Selective reporting (reporting bias)	Low risk	The clinical trial registration number is provided.
Baseline outcomes measurement	Low risk	Comment: no P values given but sample sizes and unadjusted means for Paediatric Quality of Life Inventory were similar at baseline across all 3 groups.
Baseline characteristics	Low risk	Quote: "There were no demographic differences across conditions (Table I)."
Other bias	Low risk	Ethics: approved by the institutional review boards at Rady Children's Hospital, the RAND Corporation, and Cincinnati Children's Hospital Medical Center. Declarations of interests/disclosures: Dr Varni holds the copyright and the trademark for Paediatric Quality of Life Inventory and receives financial compensation from the Mapi Research Trust, which is a non-profit research institute that charges distribution fees to for-profit companies that use the Paediatric Quality of Life Inventory. Funding: grant from the Maternal and Child Health Bureau of the Health Resources and Services Administration (R40 MC01214/08044). The funder had no role in the design nor conduct of the study, in the collection, analysis, nor interpretation of the data, nor in the preparation, review, nor approval of the manuscript. Trial registration or protocol registration or publication: NCT00250588.

Smaldone 2018

Study characteristics	
Methods	Study design: parallel randomised controlled trial Allocation: 2:1 intervention:control

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Smaldone 2018 *(Continued)*

	Controlled: educational handouts about sickle cell + hydroxyurea + usual clinical care at monthly intervals Blinding: results only Arms: 2; control vs intervention Centre: 2 paediatric sick cell medical centres in New York Dates and follow-up: participants recruited between 4 September 2013 and 28 March 2015. Followed for 6 months.
Participants	Inclusion criteria: aged 10–18 years and parent enroled; youth with HbSS or HbS-B0 thalassemia prescribed hydroxyurea for ≥ 18 months; not cognitively impaired; youth and parent could speak/read English or Spanish and were willing to use a mobile phone; ≥ 10% decrease in their haemoglobin F from their personal best haemoglobin F during clinical care based on average of ≥ 3 haemoglobin F levels during the year prior to study enrolment Exclusion criteria: opposites of inclusion criteria Recruitment: participants recruited between 4 September 2013 and 28 March 2015. 74 screened at 2 sites, 48 met all inclusion/exclusion criteria. 28 participated in the study, attrition rate was 10.7% (2 in intervention, 1 in control; reasons for attrition were incarceration, drug use, study too burdensome by parent) **Baseline characteristics** Age (years): 14.3 (SD 2.6) Gender (female): 43% Ethnicity: 50% Hispanic Parents: 64.3% single or separated from spouse (note more married parents in intervention arm compared with control arm; P = 0.02) Parent education: high school (57%) Parent work: 71.4% full or part-time work Spanish language surveys: 42% parents, 25% children Urgent hospital use in 1 year prior to study: 60% for both groups (rate of hospitalisation or ED attendance) Haemoglobin F at baseline: although mean haemoglobin F similar, less decrease from personal best haemoglobin F in the intervention group compared with control (intervention: −18.1 (SD 23.6); control: −42.6 (SD 21.3); P = 0.009) Historical personal best haemoglobin F: similar. Intervention: 17.3 (SD 17.7); control: 16.6 (SD 3.5); P = 0.88 Significant differences between both groups at baseline: more married parents in the intervention arm, the control group had a greater difference in their personal best haemoglobin F compared to current haemoglobin F
Interventions	Prerandomisation: 48 participants; 58% (28) participated in the study **Intervention** (18 participants): during first 3 months a community health worker monthly or bimonthly visits covering social, sickle cell disease and hydroxyurea education, identify a habit that hydroxyurea could be fostered to. At 4–6 months automated text message and medication reminder. Throughout, community health worker and participants were able to contact each other via telephone or text message.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Smaldone 2018 *(Continued)*

	Control (10 participants): educational handouts about sickle cell disease, hydroxyurea, and usual clinical care at monthly intervals Co-interventions or additional treatments: none Duration of treatments and follow-up details: 6 months
Outcomes	**Primary outcomes** • Hydroxyurea adherence measured by decrease from haemoglobin F personal best at monthly intervals (0–6 months), prescription refill adherence, and 4-item modified Morisky self-report scale (score 0 = high adherence, 3–4 = low adherence) • Feasibility and acceptability measured by subject retention, monthly postcard comments from intervention group, and evaluation surveys at study completion **Secondary outcome** • Generic and disease-specific health-related quality of life and concordance regarding self-management responsibility. Youth and parents completed survey measures at 0, 3, and 6 months in either English or Spanish using Paediatric Quality of Life Inventory Generic Score Scale and Paediatric Quality of Life Inventory Sickle Cell Disease Module and Sickle Cell Family Responsibility Scale
Notes	Ethics: study procedures approved by Institutional Review Boards at each participating site. Declarations of interests/disclosures: none. Funding: NIH Grant Number R21NR013745, NIH to the Irving institute for clinical-translational science, grant number 5ULTR000040-09. Trial registration or protocol registration or publication: –

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomisation with a 2:1 allocation to the intervention by a computerised random number generator …"
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomisation with a 2:1 allocation to the intervention by a computerised random number generator …" Comment: open to tampering. Did not explain who was responsible for this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Subjects were blinded to study hypotheses, although not to group allocation." Comment: unable to keep intervention allocation concealed.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no mention if outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "74 screened at 2 sites, 48 met all inclusion/exclusion criteria. 28 participated in the study, attrition rate was 10.7% (2 in intervention, 1 in control; reasons for attrition = incarceration, drug use, study considered too burdensome by parent)."
Selective reporting (reporting bias)	Low risk	Trial protocols published and trial registered on Clinical Trials.gov.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Smaldone 2018 *(Continued)*

Baseline outcomes measurement	High risk	Comment: table 2 of publication suggests a significant difference between percentage decrease from personal best in control group (−42.6) vs intervention group (18.1) (P = 0.009). Study investigators did not mention any further analysis to adjust for the differences. Study investigators suggested that the bias introduced was uncertain and suggested that young people starting at lower haemoglobin F levels may have been more resistant to change in adherence.
Baseline characteristics	Low risk	Quote: "The multiethnic sample of 28 dyads was similar in most demographic characteristics (Table 1). On average, youth were 14.3 ± 2.6 years old, 43% female and 50% Hispanic. The majority (64.3%) of parents were single and/or separated from a spouse, had a high school education or less (57%), and were employed full or part-time (71.4%). Spanish language surveys were selected for use by 42% of parents and 25% of youth."
Other bias	Low risk	Ethics: study procedures approved by Institutional Review Boards at each participating site. Declarations of interests/disclosures: none. Funding: NIH Grant Number R21NR013745, NIH to the Irving institute for clinical-translational science, grant number 5ULTR000040-09. Trial registration or protocol registration or publication: –

Spaic 2019

Study characteristics	
Methods	Study design: parallel randomised controlled trial Allocation: 1:1 ratio Controlled: standard care for transition to adult services Blinding: due to the nature of intervention, not possible to blind to allocation. Data analysis and outcome assessors were blind to group assignment Arms: 2; standard care (control) vs transition co-ordinator (intervention) Centre: multicentre study (3 paediatric centres); 2 tertiary, 1 secondary Dates and follow-up: 18 months with intervention group transition co-ordinator, 12 months with standard care
Participants	Inclusion criteria: aged 17–20 years; established type 1 diabetes mellitus for ≥ 1 year; ≥ 1 visit in the previous year by a paediatric endocrinologist at 1 of 3 participating diabetes clinics; ability to participate in all aspects of clinical trial; written informed consent/assent obtained and documented; resident of Ontario, Canada Exclusion criteria: people unable to independently manage their diabetes; intellectual disability requiring caregiver assistance with diabetes mellitus management; people with ongoing medical issues that interfered with diabetes care and glycaemic control (e.g. high-dose steroid treatment, active cancer treatment); pregnancy (or intent to become pregnant in the coming 3 years); participation in another clinical trial currently or in the previous 6 months; prior enrolment of a sibling in the study **Baseline characteristics** Age (years): 17.9 (SD 0.6) Gender (male, number): transition co-ordinator: 57; standard care: 47

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Spaic 2019 *(Continued)*

	Ethnicity • Caucasian: transition co-ordinator: 90; standard care: 85 • African American: transition co-ordinator: 7; standard care: 4 • Asian or Pacific Islander: transition co-ordinator: 2; standard care: 4 • Other: transition co-ordinator: 5; standard care: 8 Time since diabetes diagnosis (years): transition co-ordinator: 8.5 (SD 4.1); standard care: 7.7 (SD 4.3) Age at diabetes mellitus diagnosis (years): transition co-ordinator: 9.4 (SD 4.2); standard care: 10.1 (SD 4.2) Education • High school (enroled or graduated): transition co-ordinator: 82 (79%); standard care: 83 (82%) • High school (dropout): transition co-ordinator: 3 (3%); standard care: 2 (2%) • College: transition co-ordinator: 8 (8%); standard care: 10 (10%) • University: transition co-ordinator: 9 (9%); standard care: 6 (6%) • Homeschooled: transition co-ordinator: 2 (2%); standard care: 0 (0%) Family structure • Single parent: transition co-ordinator: 22 (21%); standard care: 26 (26%) • 2 parents: transition co-ordinator: 75 (72%); standard care: 73 (72%) • Other: transition co-ordinator: 7 (7%); standard care: 2 (2%) Current smoker: transition co-ordinator: 6 (6%); standard care: 9 (9%) Alcohol use (≥ 3 units/week): transition co-ordinator: 12 (12%); standard care: 8 (8%) Cannabis use: transition co-ordinator: 12 (11%); standard care: 13 (13%) Setting: outpatient Location: Canada Significant differences between groups at baseline: none
Interventions	**Intervention** (104 participants): transition co-ordinator for 6 months for children then 12 months for adults (18-month total follow-up) **Control** (101 participants): standard care Co-interventions or additional treatments: none Duration of treatment and follow-up details: 18 months of intervention with transition co-ordinator or 12 months of standard adult care; follow-up period was 12 months after intervention period.
Outcomes	**Primary outcome** • Proportion of participants failing to attend ≥ 1 adult outpatient department during the 12-month study **Secondary outcome** • Frequency of HbA1c testing • Mean HbA1c level • Frequency of complications screening for diabetes • Diabetes-related ED presentations and hospitalisations for diabetic ketoacidosis and hypoglycaemia • Participant satisfaction with transition process • Diabetic distress and impact on quality of life

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Spaic 2019 *(Continued)*

Notes	Ethics: not reported. Declarations of interests/disclosures: authors listed personal fees and grants from multiple pharmaceutical companies. Funding: funded by JDRF (CCTN1102) and grants from the JDRF Canadian Clinical Trials Network, Western University. Trial registration or protocol registration or publication: NCT01351857. Additional: we attempted to contact the corresponding author to obtain diabetes-related ED presentations and hospitalisation rates for chronic kidney disease and hypoglycaemia, but received no response.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants randomly assigned to 1:1 ratio to the transition programme or standard care. Randomisation schedule was computer generated in variable blocks stratified by HbA1c (< 8.5 mmol or ≥ 8.5 mmol) and site and held centrally at the data coordinating centre.
Allocation concealment (selection bias)	Low risk	Because of the nature of the intervention, they could not blind participants and members of the diabetes treatment team to group allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Because of the nature of the intervention, they could not blind participants and members of the diabetes treatment team to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessors and data analysis personnel were blinded to the group assignment.
Incomplete outcome data (attrition bias) All outcomes	High risk	20% attrition in control and 20% attrition in intervention group (40% lost to follow-up). No mention from authors regarding why there was attrition for any outcome.
Selective reporting (reporting bias)	Low risk	Protocol published in 2013. Trial registered and number provided.
Baseline outcomes measurement	Low risk	Quote: "Four mixed logistic regression models were used to analyse the effect of the intervention adjusted for the study period and baseline HbA1c." Comment: baseline HbA1c levels appeared similar although P values not given.
Baseline characteristics	Low risk	Quote: "Baseline characteristics were similar between groups (Table 1)."
Other bias	Low risk	Ethics: ethics approval and consent to participate. Prior to recruitment, the study was approved by the institutional review board at Columbia University Medical Center (Protocol number AAAR2908) and at each participating clinical site. Prior to study participation, eligible parent–youth dyads willing to participate will sign a written consent or assent (or both). The consenting process will be conducted in either Spanish or English depending on dyad preference.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Spaic 2019 *(Continued)*

	Declarations of interests/disclosures: authors listed personal fees and grants from multiple pharmaceutical companies. Funding: JDRF (CCTN1102) and grants under the JDRF Canadian Clinical Trials Network, Western University. Trial registration or protocol registration or publication: NCT01351857.

Svoren 2003

Study characteristics	
Methods	Study design: parallel randomised controlled trial Allocation: 1:1:1 Controlled: standard care Blinding: of statisticians only. Could not blind participants Arms: 3; care ambassador vs care ambassador + psychosocial intervention vs standard care Centre: single centre (Joslin Diabetes Center, Harvard) Dates and follow-up: 2-year follow-up (no specific dates)
Participants	Inclusion criteria: aged 7–16 years with type 1 diabetes mellitus for > 6 months; ≥ 1 outpatient department medical visit in past year; no major psychological issues in participant/parent; stable living environment Exclusion criteria: none of the above Recruitment: 299 total; 301 initially randomised, 2 discontinued and thus excluded **Baseline characteristics** Age mean (years): overall: 11.87 (SD 2.49); standard care: 11.7 (SD 2.6); care ambassador: 11.8 (SD 2.4); care ambassador + psychosocial: 12.1 (SD 2.4) Gender (male): standard care: 49%; care ambassador: 39%; care ambassador + psychosocial: 42% Ethnicity: no data Length of type 1 diabetes mellitus (years): overall: 5.22 (SD 2.94); standard care: 5.3 (SD 3.0); care ambassador: 5.1 (SD 2.9); care ambassador + psychosocial: 5.3 (SD 3.0) HbA1c: overall: 8.66% (SD 1.17); standard care: 8.72 (SD 1.17); care ambassador: 8.57 (SD 1.35); care ambassador + psychosocial: 8.68 (SD 1.03) No significant differences between the groups, for age/sex/body mass index/duration, type 1 diabetes mellitus/HbA1c/insulin dose and frequency of blood glucose monitoring Setting: outpatient diabetes centre Location: Joslin Diabetes Center
Interventions	Prerandomisation: 299 (301, 2 dropped out) **Intervention 1** (94 participants): care ambassador. Psychoeducational modules – written teaching modules addressing 8 issues pertaining to diabetes care. Care ambassadors implemented these modules at each visit with scripted protocol to ensure consistency of intervention delivery. Families were given written information and care ambassador encouraged active family discussion around topics.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Svoren 2003 *(Continued)*

	This extended care ambassador time with family by 15–30 minutes per visit. Families took home written materials post each session. **Intervention 2** (97 participants): care ambassador (as for group 1) + psycho-educational support. **Control** (108 participants): standard care (annual contact by telephone to check outcomes only) Co-interventions or additional treatments: – Duration of treatments and follow-up details: 2-year follow-up (12 months, 24 months). Care ambassador group had a mean of 7.3 visits, care ambassador + psychosocial had 7.5 visits, 5.4 visits for standard care group (P = 0.001). No significant difference between care ambassador and care ambassador + psychosocial groups (P = 0.48). ≤ 3 visits per year, 4 care ambassador, 6 care ambassador + psychosocial, 24 standard care group (P = 0.001).
Outcomes	**Primary outcomes** • Glycaemic control – HbA1c • Frequency of hypoglycaemic episodes • Hospitalisations/ED attendance (diabetic and non-diabetic) **Secondary outcomes**: none
Notes	Ethics: study protocol approved by the Committee on Human studies at Joslin Diabetes Centre. Declarations of interests/disclosures: not reported. Funding: grant (DK-46887) from the National Institute of Diabetes and Digestive and Kidney Diseases, the Charle H Hood Foundation and the Katherine Adler Astrove Youth Education Fund. Trial registration or protocol registration or publication: DOI: 10.2147/clep.s48870.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "We randomly assigned the patient to 1 of 3 study conditions for the prospective trial …" Comment: no information regarding randomisation process provided.
Allocation concealment (selection bias)	Unclear risk	Quote: "We randomly assigned the patient to 1 of 3 study conditions for the prospective trial …" Comment: no information regarding randomisation process provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: participants could not be blinded to their allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "An interval history including assessment of outcomes and a physical examination were also completed for all patients at each visit by a clinician who was blinded to group assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Figures reported for each outcome separately (e.g. 293/299 patients had data on hypos – 6 patients no data (1 SC [standard care], 1 CA [care ambassador], 4 CA+ [care ambassador + psychosocial intervention]) but no mention of why no data for these 6 patients)." Comment: no mention of why no data for these participants.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Svoren 2003 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	No trial registration or protocol information provided.
Baseline outcomes measurement	Low risk	Quote: "There were no significant differences between the study groups at baseline with respect to age, sex, body mass index, duration of diabetes, HbA1x, insulin dosage in U/kg/d, and frequency of daily blood glucose monitoring."
Baseline characteristics	Low risk	Quote: "There were no significant differences between the study groups at baseline with respect to age, sex, body mass index, duration of diabetes, HbA1x, insulin dosage in U/kg/d, and frequency of daily blood glucose monitoring."
Other bias	Unclear risk	Ethics: study protocol approved by Committee on Human studies at Joslin Diabetes Center. Declarations of interests/disclosures: not reported. Funding: supported by a grant (DK-46887) from the National Institute of Diabetes and Digestive and Kidney Diseases, the Charle H Hood Foundation and the Katherine Adler Astrove Youth Education Fund. Trial registration or protocol registration or publication: DOI: 10.2147/clep.s48870.

Weinstein 2021

Study characteristics	
Methods	Study design: randomised controlled trial Allocation: 1:1 Controlled: yes Blinding: yes Arms: 2; asthma education (control) vs community health worker (intervention) Centre: 6 clinics in Chicago and Evanston, Illinois, USA Dates and follow-up: 18 months
Participants	Inclusion criteria: aged 5–16 years; living with a carer ≥ 5 days per week; having uncontrolled asthma measured by the Asthma Control Test or childhood Asthma Control Test, the Asthma Control Questionnaire, and self-report of ≥ 1 oral corticosteroid burst in the past year; 1 child per household could be enroled Exclusion criteria: lack of fluency in English or Spanish; transient living conditions; child having significant developmental delays or comorbidities limiting their ability to participate Recruitment: March 2016 to August 2017. By screening Erie electronic medical records for asthma diagnosis and sending letters/telephone calls, or by direct recruitment by Erie providers and staff, or by posters/flyers Setting: Erie Family Health Center Location: Chicago and Evanston, Illinois Significant differences between groups at baseline: no

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Weinstein 2021 *(Continued)*

Baseline characteristics

Age (years): overall: 94 (SD 3.0); control: 9.5 (SD 3.2); community health worker: 9.3 (SD 2.9)

Gender female (number): overall: 98 (44.0%); control: 52 (45.2%); community health worker: 45 (42.6%)

Caregiver is parent (number): overall: 216 (96.9%)

Ethnicity (number)

- Black: overall: 39 (17.6%); control: 21 (18.4%); community health worker: 18 (16.7%)
- White: overall: 63 (28.4%); control: 30 (26.3%); community health worker: 33 (30.6%)
- Hispanic: overall: 190 (85.2%); control: 98 (85.2%); community health worker: 92 (95.2%)

Child baseline asthma control uncontrolled by Asthma Control Test or childhood Asthma Control Test: overall: 123 (55.7%); control: 59 (51.3%); community health worker: 64 (60.4%)

Days of activity limitation in the last 2 weeks: overall: 3.6 (SD 3.9); control: 3.4 (SD 4.0); community health worker: 3.7 (SD 3.9)

ED visits in 12 months: overall: 2.1 (SD 1.5); control: 2.2 (SD 1.5); community health worker: 1.9 (SD 1.4)

Hospitalised for asthma in 12 months: overall: 1.5 (SD 1.1); control: 1.2 (SD 0.5); community health worker: 2.1 (SD 1.8)

Oral corticosteroid bursts for asthma in 12 months: overall: 2.1 (SD 1.6); control: 2.1 (SD 1.4); community health worker: 2.1 (SD 1.8)

Caregiver education

- Less than high school: overall: 64 (28.7%); control: 33 (28.7%); community health worker: 31 (28.7%)
- High school or GED (equivalent diploma): overall: 84 (37.7%); control: 42 (36.5%); community health worker: 42 (38.9%)
- Vocational/college: overall: 54 (24.2%); control: 28 (24.4%); community health worker: 26 (24.1%)
- College graduate or higher: overall: 21 (9.4%); control: 12 (10.4%); community health worker: 9 (8.3%)

Household income in the last year (%) (total of both groups): < USD 20,000: 46 (20.9%), USD 20,000–59,000: 91 (41.4%), > USD 60,000: 13 (5.9%); unknown: 70 (31.8%)

Language of interview (number)

- English: overall: 109 (48.9%); control: 57 (49.6%); community health worker: 52 (48.2%)
- Spanish: overall: 70 (31.4%); control: 36 (31.3%); community health worker: 34 (31.5%)
- Mixed: overall: 44 (19.7%); control: 22 (19.1%); community health worker: 22 (20.4%)

Born outside of mainland USA: overall: 121 (54.3%); control: 62 (53.9%); community health worker: 59 (54.6%)

Relationship (number living with partner/spouse): overall: 144 (65.2%); control: 75 (65.8%); community health worker: 69 (64.5%)

Child body mass index category (total of overweight 85–95% and ≥ obese 95%); control: 46 (20.6%); community health worker: 85 (38.1%)

Asthma education control intervention: none: 56 (48.7%); initial session: 52 (45.2%); initial follow-up 23 (20.0%); 6-month clinic session: 32 (27.8%); 6-month follow-up telephone call 15 (13%)

Community health worker intervention: no visits: 5 (5.6%); 1–3 visits: 10 (9.3%); 4–6 visits: 23 (21.3%); 7–9 visits: 59 (54.6%); ≥ 10 visits: 10 (9.3%)

Interventions	Prerandomisation: 225 participants; 54 excluded out of qualified participants due to baseline visit not scheduled 20, baseline visit not completed 25, ineligible between screening and enrolment 6, caregiver did not consent 3

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Weinstein 2021 *(Continued)*

	Excluded after enrolment: consent form not completed 1, did not complete data collection 1 **Intervention** (108 participants): community health worker **Control** (115 participants): asthma education Duration of treatments and follow-up details: 12 months, follow-up to 24 months after intervention completed.
Outcomes	**Primary outcomes** • Asthma control using Asthma Control Test or childhood Asthma Control Test • Mean days with activity limitation over 14 days (community health worker is more effective if the intervention arm is 30% lower than asthma education control) **Secondary outcomes** • Maintenance of intervention efficacy (at 18 and 24 months) • Cost-effectiveness • Assess the efficacy of intervention as demonstrated by asthma control amongst those experiencing depression, stress, or post-traumatic stress disorder
Notes	Ethics: University of Illinois at Chicago, Rush University Medical Center and NorthShore University Health System IRB and Erie Research Committee all approved the study protocol. Data Safety Monitoring Board provided oversight for the trial. Declarations of interests/disclosures: G Mosnaim received research grant support from AstraZeneca, GlaxoSmithKline, and Propeller Health; has owned stock in Electrocore; and has served as a consultant or member of a scientific advisory board for GlaxoSmithKline, Sanofi-Regeneron, Teva, Novartis, AstraZeneca, Boehringer Ingelheim and Propeller Health. AA Pappalardo is a consultant for Optum Rx/United Health Group and had a relationship ending in 2017 as a speaker for Boehringer Ingelheim. MA Martin and AA Pappalardo are on the board of directors of the Chicago Asthma Consortium. Funding: NIH, NHLBI (R01HL123797). Trial registration or protocol registration or publication: NCT02481986.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was conducted in a 1:1 ratio using randomly mixed permutation blocks of size four and six."
Allocation concealment (selection bias)	Low risk	Quote: "Upon completion of the randomization assignment, the data management team generated a letter to the participant that informed him/her of their study status and also notified the Erie AE-C [asthma education control] who assigned the patient to a CHW [community health worker] if randomized to that arm."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "blinding was maximised by the following four strategies: 1) incomplete disclosure of study goals for participants during consent 2) blinding outcomes assessors 3) incomplete disclosure of research hypotheses for non-investigator staff and 4) training so investigators and staff in the concept of equipoise.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Intervention investigators and staff were unblinded to treatment arm because they needed to work with the CHWs [community health worker] and monitor intervention fidelity and data accuracy. Study staff and investigators did not have access to interim outcomes data.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Weinstein 2021 *(Continued)*

		Data collection team was completely separate from the intervention team."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "AE-C intervention [asthma education control] None 56 (48.7) Initial session 52 (45.2) Initial follow up 23 (20.0) 6 mo [month] clinic session 32 (27.8) 6 mo follow up phone call 15 (13) CHW [community health worker] intervention No visits: 5 (5.6) 1-3: 10 (9.3) 4-6: 23 (21.3) 7-9: 59 (54.6) >/= 10: 10 (9.3)" "almost half of this group got no intervention, which makes it difficult to understand the actual intervention impact."
Selective reporting (reporting bias)	Low risk	Asthma Action at Erie Trial (NCT02481986)
Baseline outcomes measurement	Unclear risk	Comment: study did not mention differences or clarify P values, but hospitalisation for asthma was 1.2 (SD 0.5) in asthma education group vs 2.1 (SD 1.8) in the community health worker group. Study did not address the difference in baseline outcome measures. Study did note that numbers were insufficiently powered to detect differences in health care utilisation outcomes.
Baseline characteristics	Low risk	Quote: "Demographics reflected the service populations of Erie and did not differ by treatment group (Table 1)."
Other bias	Low risk	Ethics: University of Illinois at Chicago, Rush University Medical Center, and NorthShore University Health System IRB and Erie Research Committee all approved the study protocol. Data Safety Monitoring Board provided oversight for the trial. Declarations of interests/disclosures: G Mosnaim received research grant support from AstraZeneca, GlaxoSmithKline, and Propeller Health; has owned stock in Electrocore; and has served as a consultant or member of a scientific advisory board for GlaxoSmithKline, Sanofi-Regeneron, Teva, Novartis, Astra Zeneca, Boehringer Ingelheim and Propeller Health. AA Pappalardo is a consultant for Optum Rx/ United Health Group and had a relationship ending in 2017 as a speaker for Boehringer Ingelheim. MA Martin and AA Pappalardo are on the board of directors of the Chicago Asthma Consortium. Funding: NIH, NHLBI (R01HL123797). Trial registration or protocol registration or publication: NCT02481986.

White 2017

Study characteristics	
Methods	Study design: parallel randomised controlled trial Allocation: 1:1 Controlled: current care Blinding: no blinding Arms: 2; intervention vs usual care Centre: single centre (Department of Paediatric Endocrinology, Royal Children's Hospital Melbourne, Australia) Dates and follow-up: recruitment from 4 January to 31 December 2014, intervention 0–12 months, follow-up to 24 months.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

White 2017 *(Continued)*

Participants	Inclusion criteria: aged 17–19 years Exclusion criteria: non-type 1 diabetes mellitus; non-English speaking; previous referral to a private practice or referral centre outside of Melbourne; presence of complex medical condition that required regular inpatient or outpatient contact with non-diabetes hospital departments Recruitment: 218 transitioned; 165 eligible; 121 recruited (35 not approached, 9 declined); 1 subsequently unable to contact; 120 assigned **Baseline characteristics** Age (years): overall: 18.8 (SD 0.6); intervention: 18.9 (SD 0.6); control: 18.8 (SD 0.7) Gender (female): overall: 51%; intervention: 52%; control: 50% HbA1c: 8.5%: overall: 1.6%; intervention: 8.6 (1.6%); control: 8.4 (1.6%) Significant differences between both groups at baseline: mentioned no differences; P values not reported
Interventions	**Intervention** (60 participants) **Control** (60 participants): usual care
Outcomes	**Primary outcomes** • Mean frequency of adult clinic attendance during 0–12 months after transition • Disengagement from services during 0–12 months after transition **Secondary outcomes** • Mean frequency of adult clinic attendance during 12–24 months after transition • Disengagement from services during 12–24 months after transition • HbA1c concentration during 0–12 months after transition • Glycaemic control in the 12–24 months after transition • Intensity of case management • Participant satisfaction questionnaire
Notes	Ethics: "… the study was approved by the institutional ethics committees for all participating centres." Declarations of interests/disclosures: no competing interests disclosed. Funding: Australasian Paediatric Endocrine Group and Lilly (research grant 2012). Trial registration or protocol registration or publication: ACTRN12611001012965. Additional: we contacted the first author of this paper to request the proportion of participants aged < 19 years at enrolment and information about a parallel psychosocial study which may have contained some outcome measures of interest to us. She confirmed that > 50% of participants were < 19 years at enrolment.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A statistician not directly involved in the analysis of study results prepared the randomisation schedule." Comment: no clear randomisation process described.
Allocation concealment (selection bias)	High risk	Quote: "… using sequential sealed opaque envelopes."

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

White 2017 *(Continued)*

		Comment: open to deliberate tampering.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Masking of randomisation outcome was not appropriate for either the investigators or the participants." Comment: not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no mention of attempt to blind outcome assessors; however, the study only had 3 investigators, with the primary investigator taking responsibility for the integrity and accuracy of the results.
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "11 withdrew from intervention in year 1, then 10 had <2 years follow up data, 7 withdrew in year 2. 5 withdrew from control in year 1, then 10 had <2 years follow up data and 8 withdrew in year 2." Comment: high dropout rate. Investigators attempted to address this with modelling.
Selective reporting (reporting bias)	Low risk	Registered with Australian New Zealand Clinical Trials Registry (ACTRN12611001012965)
Baseline outcomes measurement	Low risk	Quote: at the time of transition, baseline characteristics including mean age and glycaemic control (HbA1c) were similar between groups (table 1).
Baseline characteristics	Low risk	Quote: "No baseline differences were seen between those who withdrew from the trial and those included for analyses (appendix)."
Other bias	Low risk	Ethics: approved by the institutional ethics committees for all participating centres. Declarations of interests/disclosures: no competing interests disclosed. Funding: Australasian Paediatric Endocrine Group and Lilly (research grant 2012). Trial registration or protocol registration or publication: ACTRN12611001012965.

Ye 2013

Study characteristics	
Methods	Study design: randomised controlled trial Primary study: – Allocation: 1:1 Controlled: active comparator Blinding: due to the nature of intervention, unable to blind participants. Study data collection was blind. Statistician was blinded Arms: 2; standard care vs intervention Centre: single centre Setting: outpatient Location: Ontario, Canada

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Ye 2013 *(Continued)*

	Dates and follow-up: recruitment May to December 2017, follow-up 2 years
Participants	Inclusion criteria: any of the following: cerebral palsy, brain injury, developmental difficulties, Down syndrome, spina bifida, autism, physical disability, developmental disability, pervasive developmental disorder, or a chronic medical condition Exclusion criteria: any of the following: palliative care, requiring emergency services, or living outside the region, or non-English speaking families without an English translator Recruitment: initial contact by mail, containing study information, parental contact and participant contact information form. 2nd mailout to families who did not respond first. Only children whose parents provided written informed consent could participate. Recruitment: overall: 229; intervention: 216; control: 445 **Baseline characteristics** Age mean (years): intervention: 7.8 (SD 4.3); control: 8.1 (SD 4.6) Gender (male); intervention: 64.6%; control: 69% Ethnicity: no data Child's psychological score (mean): intervention: 59 (SD 18.6); control: 59.2 (SD 18.6) Parent age mean (years): intervention: 40.5 (SD 7.6); control: 40.4 (SD 7.7) Marital status • Married: intervention: 83%; control: 86.6% • Other: intervention: 17%; control: 13.4% Parent education frequency • Secondary: intervention: 36.4%; control: 36.1% • Postsecondary: intervention: 63.6%; control: 63.9% Family annual income • < USD 30,000; intervention: 14%; control: 14.9% • USD 30,000–90,000: intervention: 53.1%; control: 53% • > USD 90,000; intervention: 32.9; control: 32.1 Parent's Kessler distress score (mean): intervention: 19.5 (SD 5.8); control: 20.4 (SD 7.2) Positive parenting score (mean): intervention: 15.2 (SD 3.1); control: 15.1 (SD 3.0) Social support score (mean): intervention: 17.6 (SD 4.7); control: 17.5 (SD 4.3) Family functioning score (mean): intervention: 9.1 (SD 6.3); control: 9.4 (SD 5.9) Comorbidities • Mental and developmental disorders: intervention: 46.3%; control: 44% • Nervous system disorders: intervention: 23.1%; control: 23.6% • Congenital abnormalities: intervention: 17%; control: 15.7% No differences between both groups at baseline
Interventions	Prerandomisation: 445 participants; excluded 1874/2319 **Intervention** (229 participants): service navigator conducted a comprehensive assessment to identify the child's health conditions. Trained service co-ordinator and individualised team of service providers according to the child's health and social needs.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Ye 2013 *(Continued)*

	Control (216 participants): family co-ordinated care Duration of treatment and follow-up details: 2 years
Outcomes	**Primary outcome** • Change in the child's psychosocial quality of life (using the Short Form Paediatric Quality of Life Inventory) **Secondary outcomes** • Parental distress score • Positive parenting score • Social support score • Family function score
Notes	Ethics: no known harms or safety risks. The research ethics board of Hamilton Health Sciences/McMaster Health Sciences approved this study. Declarations of interests/disclosures: authors reported no conflicts of interest. Funding: Father Sean O'Sullivan Research Centre studentship award, the Canadian Institute of Health Research Training award in Bridging Scientific Domains for Drug Safety and Effectiveness, and the Canadian Network and Centre for Trials Internationally programme. Trial registration or protocol registration or publication: DOI: 10.2147/clep.s48870.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Children were stratified by region (Simcoe/York), Community Care Access Centre, and age (pre-school/school). They were randomized within stratum by using a block size of six."
Allocation concealment (selection bias)	Low risk	Quote: "The randomization list was generated by the Health and Social Service Utilization Research Unit at McMaster University. The allocation codes were then sequentially linked to the patient IDs. Only the statistician responsible for randomisation had access to the allocation codes."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants could not be blinded to the allocation of intervention vs in this study design.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Trained interviewers … who were blinded to group allocation … After enrollment, children remained anonymous and identified by patient IDs … The data analyst was blinded to group allocation; however the participants were aware of their allocation."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "… 64 (28%) children in the intervention group and 57 (26%) children in the control group were lost to follow-up." "53 children in the CTN group did not have a team of service providers assembled or did not have the services available for their specific needs. Another 58 children in the CTN group withdrew from CTN integrated care." Comment: large number of children who could not access appropriate care/withdrew from study.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Ye 2013 *(Continued)*

Selective reporting (reporting bias)	Low risk	Clinical trial protocol NCT01379443.
Baseline outcomes measurement	Low risk	Comment: "Table 1-2" Child psychosocial score were not different at baseline between intervention and control groups.
Baseline characteristics	Low risk	Quote: "The results of this comparison are reported in Table 2. From the comparison, we did not find any significant differences between treated and untreated children except for parenting style (mean difference 1.4; P = 0.02); however, a mean difference of 1.4 on a score ranging from 0 to 20 did not seem to be a clinically relevant association."
Other bias	Low risk	Ethics: no known harms or safety risks. Research ethics board of Hamilton Health Sciences/McMaster Health Sciences approved. Declarations of interests/disclosures: authors reported no conflicts of interest. Funding: Father Sean O'Sullivan Research Centre studentship award, the Canadian Institute of Health Research Training award in Bridging Scientific Domains for Drug Safety and Effectiveness, and the Canadian Network and Centre for Trials Internationally programme. Trial registration or protocol registration or publication: DOI: 10.2147/clep.s48870.

ED: emergency department; HbA1c: glycated haemoglobin; NICU: neonatal intensive care unit; SD: standard deviation; USD: United States dollars.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
ACTRN12622000478718	Ineligible intervention
Aish 2017	Ineligible intervention
Arora 2015	Ineligible study design
Barrera 2020	Ineligible intervention. Psychosocial navigator in this context is more like a screening and triaging tool to tailor recommendations of psychosocial support to risk of psychosocial distress.
Berg 2022	Ineligible comparator
Campbell 2015	Ineligible intervention
Chen 2022	Ineligible intervention
Chernoff 2002	Ineligible intervention
Chu 2015	Systematic review. Effect of transition interventions on care transfer
Coombes 2018	Systematic review. Extensive systematic search was conducted of 9 electronic databases to identify primary studies that explored factors affecting access to ongoing services for First Nation children with a chronic disease or injury.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Study	Reason for exclusion
Fernandez-Ruiz 2021	Ineligible intervention. Intervention involved interdisciplinary team approach vs patient navigation.
Flynn 2022	Systematic review
Garcia-Rodriguez 2022	Systematic review
Geldsetzer 2017	Adult population
Goff 2013	Ineligible patient population. No chronic illness/ preventive study
Golfenshtein 2016	Systematic review
Grady 2019	Ineligible intervention. Adult population (aged > 18 years). More of an education intervention where a heart transplant co-ordinator supported education/learning with predefined number of telephone calls.
ISRCTN13535901	Ineligible intervention. A combination of an online self-management programme consisting of 12 modules for teenagers and 2 for parents, with telephone support from a health coach (trained, adult non-healthcare professionals without arthritis). iPeer2Peer is an online peer mentoring programme (support).
Jackson 2007	Ineligible intervention. Families in the experimental group were contacted by the diabetic nurse case manager by telephone weekly for 8 weeks and then monthly thereafter until 6 months after diagnosis. During both the telephone follow-up and the visit, parents received the same focused interview as used with the standard group. The child was also interviewed following the parent using the guide with prompts elicited from the parental interview. All interviews were tape-recorded for transcription. Although the nurse was a case-manager, the study did not specifically study the intervention of patient navigation.
Jonas 2022	Ineligible intervention. Intervention involves education only, without health navigation.
Kaslow 2000	Ineligible intervention. Educational vs health navigation. The study evaluated the efficacy of a family psychoeducational intervention for youth with sickle cell disease and their parents or primary caregivers. Effects were examined on disease knowledge, psychological adjustment, family and social functioning, and social support. 39 African American 7- to 16-year-old children with sickle cell disease were randomly assigned to participate in the 6-session experimental intervention or a treatment as usual control condition. A treatment manual accompanied the intervention, and included presentation of the sessions in detail, review of home activities, didactics, and activities.
Krieger 2002	Ineligible intervention. Education vs patient navigation
Lemke 2018	Proportion of children recruited aged ≤ 18 years was < 50%.
Le Roux 2017	Systematic review. Assessing programmes of transition from paediatric to adult care programmes
Leung 2020	Ineligible intervention. Nurse transition co-ordinator was part of a multipronged intervention, which also included joint paediatric/adult clinics and having clinics in the same place.
Lewin 2005	Cochrane review. To assess the effects of lay health workers in primary and community health care on healthcare behaviours, patient's health and well-being, and patient's satisfaction with care.
Mackie 2014	Ineligible intervention. The focus was on a single education session. Neither follow-up nor ongoing navigator-like support mentioned.
Mackie 2018	Ineligible intervention. 2 education intervention sessions, no navigation

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Study	Reason for exclusion
MacKie 2019	Ineligible intervention. Single education session
Mardhiyah 2022	Systematic review
McBrien 2018	Systematic review. Patient navigator programmes in people with a broad range of chronic diseases
Morisaki-Nakamura 2022	Ineligible intervention. The transitional support programme included 3 important aspects: 1. the participants attended a transitional support outpatient clinic without their guardian(s); 2. health-care professionals asked the patients questions using a common inquiry sheet; 3. the participants were asked to make "my health passport" to summarise the information of their disease after the first visit.
Nansel 2009	Ineligible intervention. Patient education vs patient navigation
NCT01511341	Ineligible intervention. Intervention: education and decision-making about treatment. The nurses were specialised in paediatric rheumatology and it was not about navigating the system.
NCT01521247	Ineligible intervention. Asthma education programme
NCT01587105	Ineligible intervention. The intervention was a special clinic at Seattle Children's with case managers and a healthcare team. Not a single navigator.
NCT01659294	Adult population
NCT01792661	Adult population
NCT01900470	Adult population
NCT02114515	Adult population
NCT02141893	Ineligible intervention. Examining effect of educating healthcare staff on CALMA (a comprehensive programme aimed to increase controlled medication use and reduce asthma symptoms) vs CALMA alone. Not navigation.
NCT02197845	Adult population. Mean age 30 years, although children included, they were likely < 50% of the population.
NCT02277327	Ineligible intervention. Participants randomised to the "intervention group" will participate in a bundled intervention that includes action planning and care transitions (for those hospitalised during the study period).
NCT02331082	Ineligible intervention. For structured quality improvement, trained healthcare providers (primarily doctors from referral hospital) will serve as mentors to mid-level providers. This is training for providers.
NCT02877823	Ineligible intervention. An ongoing trial concerning healthy lifestyle intervention advice/education/support rather than patient navigators, which seems like a very small part of intervention.
NCT02944136	Adult population
NCT02960542	Adult population
NCT03028233	Ineligible intervention
NCT03066596	Ineligible intervention

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Study	Reason for exclusion
NCT03077425	Ineligible patient population. Preventive intervention
NCT03092063	Adult population
NCT03106727	Ineligible intervention
NCT03176576	Adult population aged > 18 years
NCT03178773	Adult population
NCT03196024	Ineligible intervention. Adult population
NCT03317977	Ineligible intervention
NCT03699748	Adult population
NCT03800459	Ineligible intervention
NCT03989986	Ineligible intervention
NCT03995953	Ineligible intervention
NCT04115813	Ineligible intervention. Ineligible study design. No patient navigator role mentioned. Not a randomised controlled trial.
NCT04388592	Adult population
NCT04414553	Ineligible intervention
NCT04761016	Adult population aged 18–99 years
NCT04790604	Adult population
NCT04790617	Adult population
NCT04791267	Adult population
NCT05292365	Ineligible intervention
NCT05455216	Adult population
Overbury 2021	Ineligible intervention. An education programme "GOT Transition"
Pape 2022	Adult population. Participants predominantly age > 19 years
Parker 2008	Ineligible intervention – focus on changes to environment and behaviour change
Perry 2000	Ineligible study design. Not a randomised controlled trial
Plant 2015	Majority of participants were adults.
Raphael 2013	Systematic review
Robertson 1998	Ineligible intervention

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Study	Reason for exclusion
Saarijarvi 2021	Ineligible study design
Saarijarvi 2022	Ineligible intervention
Sequeira 2015	Ineligible study design
Sparring 2018	Ineligible study design
Steinbeck 2012	Ineligible intervention
Sullivan-Bolyai 2010	Ineligible intervention
Takaro 2004	Ineligible intervention
Thomsen 2022	Ineligible intervention
Tschank 2018	Ineligible intervention
Yang 2022	Systematic review
Yun 2015	Ineligible intervention. The role of patient navigator was described as education around obesity and healthy eating (e.g. no care co-ordination).

Characteristics of studies awaiting classification *[ordered by study ID]*

ACTRN12622001459718

Methods	Study design: designed a resource pack and Community Linker programme that aims to suit the unique needs of families of children with cerebral palsy. Testing of these 2 programmes (resource pack; resource pack plus Community Linker) in a pilot research study to see if parents/caregivers find them helpful and easy to use. Primary study: – Allocation: – Controlled: – Blinding: – Arms: – Centre: Westmead, Sydney Children's Hospital, John Hunter Children's Hospital Dates and follow-up: enrolment 1 February 2023 to 30 April 2023
Participants	Inclusion criteria: parent/caregiver of a child aged 0–18 years with a confirmed diagnosis of cerebral palsy; reside in New South Wales or Australian Capital Territory; report ≥ 1 unmet social need from the following 6 items on the adapted WECARE screening tool: childcare or schooling, government benefits and vouchers, housing, food, bills, and transport Exclusion criteria: family already enroled and assigned a research participant (parent/caregiver will only be able to enrol once per family); have no mechanism for contact (telephone and email) Recruitment: if applicable
Interventions	**Intervention**: social prescribing (resource pack and Community Linker)

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ACTRN12622001459718 *(Continued)*	**Control**: resource pack
Outcomes	
Notes	Not sure if this is a randomised controlled trial.

Goyal 2022	
Methods	Study design: multicentre randomised controlled trial Primary study: – Allocation: – Controlled: usual care from paediatric site to time of transfer Blinding: none Arms: 2; control vs intervention arm (structured transition programme) Centre: – Dates and follow-up: –
Participants	Inclusion criteria: person at a participating paediatric facility with a diagnosis of type 1 diabetes mellitus for ≥ 1 year; aged 15–19.5 years; resides in Delhi National Capital Region; ≥ 1 visit during the previous year with the paediatric care provider at the participating centre; ability to participate in all aspects of the clinical trial; informed consent/assent Exclusion criteria: anticipated plan to move outside of Delhi in the next 12–24 months; current pregnancy or plan to become pregnant in the next 3 years; participation in another clinical trial within 6 months prior to enrolment; physical or psychosocial condition that may interfere with the person's ability to participate in the study Recruitment: – Baseline characteristics: – Setting: paediatric specialist care Location: New Delhi (All India Institute of Medical Sciences)
Interventions	Prerandomisation: target 156 participants **Intervention**: structured care transition programme, with follow-up 15 months. Comprising of a "pre-overlap phase" session (session 2) at the paediatric site, followed by an "overlap phase" involving 4 alternating sessions at paediatric and adult sites (sessions 3–6), which offers intervention arm participants the opportunity to gradually adjust to adult care while still maintaining care with their paediatric provider. Includes refresher course on diabetes self-management knowledge (session 1), made aware of rationale for transition, given a list of possible adult care providers, and communicated the formal cut-off at which they must transfer to an adult provider. Transfer to the adult site will occur after the last session in this phase, which involves a review of the transfer proforma by providers from the paediatric and adult sites to mark the formal transfer. During the "postoverlap phase" lasting for 1 year following the transfer, intervention group participants will receive a soft intervention in the form of telephonic messages/emails to remind participants about quarterly clinic appointments. **Control**: usual care, transfer of care at 15 months following randomisation. Includes refresher course on diabetes self-management knowledge, made aware of rationale for transition, given

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Goyal 2022 *(Continued)*

	a list of possible adult care providers, and communicated the formal cut-off at which they must transfer to an adult provider. Co-interventions or additional treatments: – Duration of treatments and follow-up details: 15 months, follow-up for further 1 year following transfer to adult health provider.
Outcomes	**Primary outcome** • Difference in clinic attendance rate at the end of 1-year post-transfer (clinic attendance over 1 year following transfer) **Secondary outcomes** • Difference in clinic attendance rate at the end of 2 years • Difference in proportion of participants with a minimum of 4 visits in the first year • Diabetes knowledge and self-management skills • Diabetes treatment satisfaction • Overall quality of life • Diabetes-related distress • Hospitalisation for acute complications • Screening for chronic diabetes complications • HbA1c
Notes	HbA1c: glycated haemoglobin.

NCT05353998

Methods	Study design: parallel randomised controlled trial Primary study: – Allocation: randomised Controlled: – Blinding: none (open label) Arms: 2; clinical decision support with sleep navigation vs clinical decision support only Centre: Children's Hospital Philadelphia Dates and follow-up: 1 August 2022 to June 2023
Participants	Inclusion criteria for caregiver–child dyads: child aged 2–17 years; child has an abnormal sleep disordered breathing screen (e.g. a positive response to whether the child snores ≥ 3 nights/week) on the sleep screener used as part of well child visit care in the Children's Hospital of Philadelphia primary care network; child receives well child care at Cobbs Creek or Karabots Children's Hospital of Philadelphia primary care network sites; parental/guardian permission (informed consent) and if applicable, child assent; caregiver participant is the parent or legal guardian of the child; caregiver aged ≥ 18 years; English-speaking Inclusion criteria for clinicians: primary care clinician practicing at Cobbs Creek or Karabots Children's Hospital of Philadelphia primary care network sites; English-speaking Exclusion criteria for caregiver–child dyads: caregiver is not the parent or legal guardian of child participant or is aged < 18 years; non-English speaking, as intervention sessions and qualitative interviews will be conducted in English; child receives well child care at a non-participating primary

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05353998 *(Continued)*

	care site at enrolment; caregivers/guardians or people who, in the opinion of the investigator, may be non-compliant with study schedules or procedures Exclusion criteria for clinicians: does not see people at Cobs Creek or Karabots Children's Hospital of Philadelphia primary care network sites; non-English speaking, as qualitative interviews will be conducted in English Recruitment: –
Interventions	Prerandomisation: target 470 **Intervention**: clinical decision support + sleep navigation **Control**: clinical decision support only Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcomes** • Clinical decision support feasibility (proportion of participants screened for sleep disordered breathing at well child visits of all those eligible for screening at well child visits over the study period) up to 12 months calculated with data from the electronic health records. • Clinician decision support acceptability up to 12 months measured through clinician-completed system usability survey (5-point Likert scale: 1 = strongly disagree; 2 = somewhat disagree; 3 = neither agree or disagree; 4 = somewhat agree; and 5 = strongly agree; range of 12–60; higher total scores indicate better acceptability) • Acceptability of the Clinical Decision Support tool up to 12 months measured by semi-structured qualitative interviews completed by the clinicians. Up to 15 primary care clinicians will be invited to participate in an interview focused on acceptability of the Clinical Decision Support tool. The interview includes multiple, open-ended questions completed by the clinician. • Sleep navigator feasibility (number of sleep navigation activities completed among those randomised to receive sleep navigation) within 8 months of baseline assessment measured using data from the sleep navigator-completed intervention-specific fidelity checklist. • Sleep navigator feasibility (sleep navigation activities completed among those randomised to receive sleep navigation) within 8 months of baseline assessment measured using data from the caregiver-completed qualitative interview. • Acceptability of the sleep navigation programme (Treatment Evaluation Inventory-Short Form) within 8 months of baseline assessment measured through the Treatment Evaluation Inventory-Short Form that has been adapted for the Sleep PASS programme. Measure rated on a 5-point Likert scale (1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; and 5 = strongly agree; range in raw score 11–55; higher total scores indicate better acceptability). • Acceptability of the sleep navigation programme (Multicultural Therapy Competency Inventory) within 8 months of baseline assessment measured using the Multicultural Therapy Competency Inventory – Client Version questionnaire that has been adapted for the Sleep PASS programme. Measure rated on a 5-point Likert scale (1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; and 5 = strongly agree; range in raw score 5–25; higher total scores indicate better outcomes). **Secondary outcomes** • Sleep speciality care referral rates through study completion (a mean of 1 year). Measured through the proportion of participants referred for specialty care of those identified with sleep disordered breathing symptoms based on well visit sleep screener over the study period. • Completion of sleep speciality care referral through study completion (a mean of 1 year). Change in referral completion for child sleep disordered breathing care will be measured through the proportion of participants randomised to sleep navigation who complete their speciality care referral of those referred to speciality care. • Caregiver knowledge of sleep disordered breathing at baseline and within 8 months of baseline assessment. The magnitude and direction of change in caregiver knowledge of sleep disordered breathing will be measured using the obstructive Sleep Disordered Breathing and Adenotonsil-

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05353998 *(Continued)*

	lectomy knowledge scale for caregivers. This measure is rated on a dichotomous scale (true/false) with a total raw score range of 0 to 39. Correct answers are summed to attain an overall percentage score representing the degree of knowledge level, with a minimum value of 0% and a maximum of 100%. A higher percentage indicates better outcomes. • Child sleep disordered breathing symptoms: Pediatric Sleep Questionnaire at baseline and within 8 months of baseline assessment. The magnitude and direction of change in child sleep will be measured through the Pediatric Sleep Questionnaire scores, the most validated questionnaire assessing children's sleep disordered breathing symptoms. This measure is rated on a dichotomous scale ("yes" = 1, "no" = 0, and "don't know" = missing). The result is a proportion that ranges from 0.0 to 1.0. Scores > 0.33 are considered positive and suggestive of high risk for a paediatric sleep-related breathing disorder. • Child sleep habits: Brief Child Sleep Questionnaire at baseline and within 8 months of baseline assessment. The magnitude and direction of change in child sleep will be measured through the Brief Child Sleep Questionnaire which assesses child sleep habits including sleep time, total sleep duration, night waking, aspects of the sleep environment, etc. The questionnaire uses a nominal scale system. Scores on each subscale and the total score are scaled from 0 to 100. Higher scores denote better sleep quality, more positive perception of child sleep, and parent behaviours that promote healthy and independent sleep. • Patient-Reported Outcomes Measurement Information System (PROMIS) sleep disturbances at baseline and within 8 months of baseline assessment. The PROMIS Sleep Disturbances survey would measure the magnitude and direction of change in child's sleep. This measure is rated on a 5-point Likert scale (1 = never; 2 = rarely; 3 = sometimes; 4 = often; and 5 = always) with a range of 8–40. The raw scores are converted to a standardised T-score, with higher scores indicating greater severity of sleep disturbance. • Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep-Related Impairment at baseline and within 8 months of baseline assessment. The PROMIS Sleep-Related Impairment survey would measure the magnitude and direction of change in child's sleep. This measure is rated on a 5-point Likert scale (1 = never; 2 = rarely; 3 = sometimes; 4 = often; and 5 = always) with a range of 8–40. The raw scores are converted to a standardised T-score, with higher scores indicating greater severity of sleep-related impairment. • Child sleep practices at baseline and within 8 months of baseline assessment. Sleep practices would be assessed using the Patient-Reported Outcomes Measurement Information System Sleep Practices survey. This measure assesses 5 sleep practices: sleep timing, sleep routines and consistency, technology use before bedtime, sleep environment, and the need for parental presence to fall asleep. This measure is rated on a nominal scale and 5-point Likert scale. Scores on each subscale and the total score are scaled from 0 to 100. Higher scores indicate better sleep practices. • Child obstructive sleep apnoea symptoms at baseline and within 8 months of baseline assessment. The change in child obstructive sleep apnoea symptoms will be measured through the 18-item Obstructive Sleep Apnea, a validated caregiver-completed questionnaire. This measure is rated on a 7-point Likert scale. Total raw score ranges from 18 to 126. Higher scores indicates worse outcomes.
Notes	

NCT05639088

Methods	Study design: intervention, parallel assignment Primary study: SHIFT study Allocation: randomised 1:1 Controlled: yes Blinding: none Arms: 2

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05639088 *(Continued)*	Centre: Virginia Commonwealth University Dates and follow-up: not yet recruited
Participants	Inclusion criteria for adolescents and young adults: type 1 diabetes diagnosis for ≥ 1 year (as documented in medical record); aged 16–22 years; English speaking; Children's Hospital of Richmond patient (Division of Pediatric Endocrinology); must have a caregiver willing to participate Inclusion criteria for caregiver: aged > 18 years; provides care to participants and willing to participate Exclusion criteria for adolescents and young adults: non-English speaking; significant psychiatric, cognitive, medical, or developmental conditions that would impair their ability to complete assessments or engage in diabetes self-care behaviours (or both) (e.g. malignancies, psychosis, intellectual disability); hospitalisation for depression, suicidal ideation, or other psychiatric disorder within the past 12 months; lifetime history of psychotic disorder; medically induced diabetes or diagnosis of diabetes other than type 1 diabetes; currently pregnant, pregnant within the past 6 months, currently breastfeeding, or planning to become pregnant within the next 12 months; another member of the household (other than the participating parent) is a participant or staff member on this study; participation in another research study that may interfere with this study; previous participation in the SHIFT pilot study Exclusion criteria for caregiver: non-English speaking; significant psychiatric, cognitive, developmental conditions that would impair their ability to complete assessments or engage in supporting the participant with diabetes self-care behaviours (or both) (e.g. psychosis, intellectual disability); another member of the home (not the participant's) is a participant/staff member on current study; participation in another research study that may interfere with current study; previous participation in SHIFT pilot study: if applicable
Interventions	**Intervention**: SHIFT2. Adolescents and young adults will engage in routine medical visits and attend 6 sessions (once per month) focused on transition preparation and diabetes management with a transition coach and will receive biweekly messages during these 6 months that encourage self-management behaviours. Parents will attend 2 sessions (months 1 and 6) with a transition coach and will receive materials, complementing their child's lesson, once per month for months 2–5 that focus on transition of their role and supporting their child's diabetes management. **Control**: treatment as usual consisting of routine medical visits and will receive education materials monthly (once per month) regarding healthcare transition and diabetes management. Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcomes** • HbA1c at 6 months assessed using a standard assay from a routine blood draw or an at-home testing kit • Change in transition readiness from baseline to 6 months measured using the Readiness Assessment of Emerging Adults with Type 1 Diabetes Diagnosed in Youth (READDY) scale, completed by participants. • Change in diabetes adherence from baseline to 6 months assessed using the Self-Care Inventory-Revised, which will be completed by both participants and caregivers. • Attendance at clinic visits at 6 months determined from medical records and assessed by the number of regularly scheduled visits attended. **Secondary outcomes** • HbA1c at 12 months assessed using a standard assay from a routine blood draw or an at-home testing kit. • Diabetes-related events at as number determined from medical records.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05639088 *(Continued)*

	• Change in transition readiness from baseline to 12 months measured using the Readiness Assessment of Emerging Adults with Type 1 Diabetes Diagnosed in Youth (READDY) scale, which will be completed by the participants. • Change in diabetes adherence from baseline to 12 months assessed using the Self-Care Inventory-Revised, which will be completed by both participants and caregivers. • Attendance at clinic visits at 12 months determined from medical records. • Change in diabetes support from baseline to 12 months assessed using the Diabetes Social Support Questionnaire – Family Version (DDSQ-Family), which will be completed by participants. • Change in diabetes distress from baseline to 12 months assessed using the Diabetes Distress Scale for type 1 diabetes, which will be completed by both participants and caregivers. Participants will complete specific versions corresponding to age (> 18 years or < 18 years) and caregivers complete their own version of the measure. • Change in self-efficacy from baseline to 12 months measured using the Self-Efficacy for Diabetes Self-Management scale, which will be completed by the participants. • Change in quality of life from baseline to 12 months measured using the T1D and Life (T1DAL), which will be completed by the participants and caregiver. **Other outcomes** • Transition status from baseline to 12 months Participants who transition from paediatric to adult type 1 diabetes care will be assessed.
Notes	US NIH Grant 1K23DK131368 HM20024552

Willems 2021

Methods	Mixed-methods (unclear if this will include a pilot randomised controlled trial)
Participants	Children with spinal muscular atrophy 1 or spinal muscular atrophy 2
Interventions	Case management
Outcomes	Caregiver quality of life Quality of care integration Use of health services Costs
Notes	Clinical trial registration: DRKS00018778.

Characteristics of ongoing studies *[ordered by study ID]*

Bollegala 2022

Study name	Multimodal intervention to improve the transition of patients with inflammatory bowel disease from pediatric to adult care: protocol for a randomized controlled trial
Methods	Study design: multicentre randomised controlled trial, interventional, parallel assignment Primary study: –

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Bollegala 2022 *(Continued)*

	Allocation: randomised Controlled: – Blinding: none Arms: 2 arms; multimodal intervention vs standard care Dates and follow-up: 25 February 2022 to 31 December 2025
Participants	Inclusion criteria: aged 16–17.5 years; diagnosed with irritable bowel disease diagnosed using standard criteria; ability to speak/read English at a functional (Grade 8) level; intention to reside in Canada after transfer to adult care; ability to use a smartphone or personal computer for the virtual intervention Exclusion criteria: do not speak English fluently; intention to leave Canada after graduation from high school Recruitment: – Location: recruitment from paediatric irritable bowel disease centres, that are part of the Canadian Children IBD Network (CIDsCaNN): BC Children's Hospital; McMaster Children's Hospital; Children's Hospital of Eastern Ontaria; SickKids
Interventions	Prerandomisation: target 115 **Intervention**: behavioural: multimodal intervention consisting of 4 core components • Core Component 1: individualised assessment: each participant will undergo individualised assessment of their biopsychosocial risk profile (PIBD INTERMED), self-efficacy (IBD-SES-A), function (IBD-DI), transition readiness (TRAQ) and IBD knowledge (IBD-KID2), and depression, anxiety, and activation. • Core Component 2: transition navigator: participants will be assigned a transition navigators, who will have knowledge of irritable bowel disease, an understanding of the care pathway involved in transitioning people with irritable bowel disease, and the skills and ability to provide psychosocial support. • Core Component 3: participant skills-building: skills-building materials delivered virtually. Navigators will also be trained as motivational coaches and will lead separate personalised virtual sessions targeting individual skills that have been identified as deficient during the assessment phase. • Core Component 4: eLearning curriculum: organised online eLearning modules with reinforcement of knowledge by the navigators. **Control**: standardised version of routine care for transition. In addition to recruiting centres' standard of care, all participating centres will implement the following transition interventions: a written letter explaining the goals of transition to the patient and family; completion of age-appropriate checklists to ensure adolescents are meeting milestones of transition (developed by the TRACC Network); annual online live educational webinars on transition and adolescent issues (hosted by the CIDsCaNN Education Committee); completion of the Pediatric INTERMED, with appropriate biopsychosocial intervention; completion of a transfer-of-care summary letter sent to the receiving adult gastroenterologist using a standardised letter template. The control group may also receive any interventions currently in place in their participating care centre, but will not receive the formal 4-component intervention described. Co-interventions or additional treatments: – Duration of treatments and follow-up details: 3 years
Outcomes	**Primary outcome** • IBD Disability Index (IBD-DI) at 3 years. Ordinal variable that measures participant functioning as the primary outcome. IBD-DI was selected as a validated measure of overall disability, functioning, and health.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Bollegala 2022 *(Continued)*

Secondary outcomes

- Transition Readiness Assessment Questionnaire at 3 years
- Transition Readiness Assessment Questionnaire up to 24 months (at time of transfer to adult care)
- Transition Success Scores at 3 years
- Transition Success Scores up to 24 months (at time of transfer to adult care)
- Pediatric IBD INTERMED at 3 years; biopsychosocial risk profile
- Pediatric IBD INTERMED up to 24 months (at time of transfer to adult care); biopsychosocial risk profile
- IBD-KID2 at 3 years; disease-related knowledge
- IBD-KID2 up to 24 months (at time of transfer to adult care); disease-related knowledge
- IBDQ-32 at 3 years; quality of life
- IBDQ-32 up to 24 months (at time of transfer to adult care); quality of life
- IBD Self-Efficacy Scale – Adolescent (IBD-SES-A) at 3 years; self-efficacy
- IBD Self-Efficacy Scale – Adolescent (IBD-SES-A) up to 24 months (at time of transfer to adult care); self-efficacy
- Physician Global Assessment at 3 years; physician assessment of disease activity
- Physician Global Assessment up to 24 months (at time of transfer to adult care); physician assessment of disease activity
- Fecal calprotectin at 3 years; measure of gut inflammation
- Modified Harvey-Bradshaw Index for Crohn's disease at 3 years; disease activity in people with Crohn's disease
- Modified Harvey-Bradshaw Index for Crohn's disease up to 24 months (at time of transfer to adult care); disease activity in people with Crohn's disease
- Pediatric Ulcerative Colitis Activity Index at 3 years; disease activity in people with ulcerative colitis
- Pediatric Ulcerative Colitis Activity Index (PUCAI) up to 24 months (at time of transfer to adult care); disease activity in people with ulcerative colitis
- Emergency department visit after 18th birthday (yes/no) at 3 years; health services utilisation
- Number of emergency department visits after 18th birthday at 3 years; health services utilisation
- Hospitalisation after 18th birthday (yes/no) at 3 years; health services utilisation
- Number of outpatient visits to a gastroenterologist after 18th birthday at 3 years; health services utilisation
- IBD Disability Index up to 24 months (at time of transfer to adult care); ordinal variable that measures participant functioning as the primary outcome. IBD-DI was selected as a validated measure of overall disability, functioning, and health.

Starting date	25 February 2022
Contact information	Eric I Benchimol; (613)8131500; eric.benchimol@sickkids.ca Jacqueline de Guzman; (416)9205035 ext 234; jdeguzman@crohnsandcolitis.ca
Notes	

Bryant-Stephens 2021

Study name	The West Philadelphia asthma care implementation study
Methods	Study design: parallel randomised controlled trial, randomisation stratified into ≥ 5 groups Primary study: – Allocation: 1:1

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Bryant-Stephens 2021 *(Continued)*

	Controlled: yes Blinding: allocation blinding Arms: 6 arms Centre: Children's Hospital Philadelphia Dates and follow-up: May 2018 to June 2022 (complete analysis by 2024)
Participants	Inclusion criteria: age 5–13 years; uncontrolled asthma (1 systemic steroid course administered for asthma flare in primary care, emergency department, or inpatient setting within the previous 12 months); lives in West Philadelphia (zip codes 19104, 19131, 19139, 19142, 19143, 19151, 19153); receive primary care at 1 of the 4 study recruitment sites Exclusion criteria: – Recruitment: sites: 3 Children's Hospital Philadelphia primary care sites, Children's Hospital Philadelphia emergency department, West Philadelphia office of the Paediatric and Adolescent Medicine Centers of Philadelphia Setting: primary care, school Location: as above
Interventions	Prerandomisation: 627 (completed enrolment 20 June 2021) 6 intervention groups: A: P+S+; B: P-S+; C: P+S-; D: P-S-; E: P+S0; F: P-S0 • Primary care intervention: P+/P- Includes asthma management education, home visits and environmental assessments, care co-ordination, school-based asthma therapy. • School Intervention: S+/S- Includes asthma management education for students with asthma, teachers and professional development for school staff, classroom visits and environmental assessments, care co-ordination • Non-participating school: S0 Co-interventions or additional treatments: – For groups D and F, offered Community Asthma Prevention Program (CAPP) asthma classes conducted at community sites (free registration) Duration of treatments and follow-up details: study data collected at 3 months, 6 months, 9 months, 12 months (12-month visit P will include spirometry and end-of study data, follow-up telephone up to 24 months)
Outcomes	**Primary outcome** • Juniper's Asthma Control Questionnaire (ACQ) at baseline, 3 months, 6 months, 9 months, 12 months **Secondary outcomes** • Symptom-free days • School absences • Healthcare utilisation (emergency department and inpatient visits) • Cost savings at baseline, 3 months, 6 months, 9 months, and 12 months
Starting date	May 2018

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Bryant-Stephens 2021 *(Continued)*

Contact information	
Notes	Ethics approval obtained Funding by Grant NHLBI#U01HL138687

Jimenez 2021

Study name	Feasibility and acceptability of a telephone-based intervention for Hispanic children to promote treatment adherence after traumatic brain injury: a pilot study.
Methods	Study design: interventional, parallel assignment Primary study: – Allocation: 1:1 Controlled: yes Blinding: single Arms: 2; intervention vs control Centre: multicentre Dates and follow-up: 7 July 2022 to March 2026
Participants	Inclusion criteria for children: aged 6–17 years; Hispanic ethnicity; diagnosis of mild-complicated, moderate, or severe telephone-based intervention; hospitalisation for > 24 hours at 1 of the 5 academic institutions participating in this trial; treatment requiring ≥ 1 type of rehabilitation therapy as outpatient Inclusion criteria for parent: Hispanic ethnicity; being the primary caregiver for the child (for longitudinal follow-up purposes) Exclusion criteria for children: prior neurological deficits; acquired brain injuries secondary to other conditions different from trauma; traumatic brain injuries secondary to abusive trauma Exclusion criteria for parent: loss of custody of the child (i.e. abusive head trauma); inability to be contacted by telephone Recruitment: – Setting: community Location: Oregon Health and Science University, Southwestern Medical Center, University of Utah, Harborview Medical Center, Seattle Children's Hospital
Interventions	Prerandomisation: target 300 participants **Intervention**: receives 1 in-person education session using the 1stBIEN booklet, video education via mobile phones and care co-ordination from a bilingual patient navigator for 3 months. Patient navigator follow-up participants weekly for the first month and once a month for 2 months. Video education weekly. Videos cover problem-solving training, brain injury concepts, rehabilitation treatments, and school resources individualised to participant and family needs. Patient navigators facilitate transition to outpatient care, follow-up with specialists and primary care providers; use of community resources; and communication with teachers and school administrators. Patient navigator provides observational and experiential learning opportunities for parents, using 3-way calls for scheduling of services and interactions with clinics and schools. Patient navigator calls use

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Jimenez 2021 *(Continued)*

a problem-solving training format, to reinforce parental experiential learning and improve self-efficacy. Expert MD providers (co-investigators) will supervise patient navigators.

Control: attention control receives 1 in-person education session using the 1stBIEN booklet, monthly well-child texts, and usual postinjury care including routine follow-up by specialists and primary care providers, per guidelines at each recruiting institution. Control participants have access to a list of community resources included in the 1stBIEN booklet. While education using the 1stBIEN booklet is not part of the current usual care at participating institutions, providing all families with initial education at the time of discharge addresses ethical and practical considerations. It standardises discharge processes at participating institutions while delineating differences in the intensity of education and care co-ordination activities.

Co-interventions or additional treatments: –

Duration of treatments and follow-up details: –

Outcomes

Primary outcomes

- Receipt of follow-up care in centralised hospital and community at 6 months after discharge measured as percentage of attended appointments at hospital, primary care, and therapies.
- Child's health-related quality of life 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Measured using the Paediatric Quality of Life Inventory. A 23-item questionnaire extensively used in telephone-based intervention outcomes studies. It assesses physical, emotional, social, and school functioning. Items on the Paediatric Quality of Life Inventory are reverse scored and transformed to a 0–100 scale. Higher scores indicate better health-related quality of life; a clinically meaningful difference is 4.5 points. Minimum score is 0 maximum score is 100.

Secondary outcomes

- Child's functional independence 24 hours before hospital discharge and through study completion a mean of 6 months measured using the Functional Independence Measures FIM (8+ years) and WeeFIM (6–7 years); 18 items (mobility: 5 items, self-care: 8 items, and cognition: 5 items) objective functional measures of independence. Every item is scored from 1 (dependent) to 7 (independent). The possible total score ranges from 18 (lowest) to 126 (highest) level of independence. For each item, scores of 1 (total assistance) and 2 (maximal assistance) belong to the 'Complete Dependence' category. Scores of 3 (moderate assistance), 4 (minimal contact assistance), and 5 (supervision or set-up) belong to the 'Modified Dependence' category. Scores of 6 (modified independence) and 7 (complete independence) belong to the 'Independent' category.
- Child's communication 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Adaptive Behavior Assessment System Third Edition (ABAS 3) – Communication subscale. A norm referenced measurement designed to assess adaptive skills. For both subscales, the mean and SD values for healthy individuals are 10 mean and 3 SD; higher scores indicate better functioning, and lower scores indicate below-average functioning.
- Child's social skills 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System (PROMIS) Parent Proxy-Peer Relationships (SF7a). Symptoms rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Child's anxiety symptoms 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System (PROMIS) Parent Proxy-Anxiety (SF8a) symptoms. Short version of PROMIS parental report paediatric measures of anxiety (8 items). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Child's pain interference 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System PROMIS Parent Proxy-Pain Interference (SF8a). pain interference (8 items). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Jimenez 2021 *(Continued)*

- Child's Physical Function – Upper Extremity 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System PROMIS Parent Proxy-Physical Function of Upper Extremity (SF8a). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Child's academic performance 1 year before the injury and 1 year after the injury; school GPA
- Child's fatigue 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System PROMIS Parent Proxy – Fatigue (SF 10a). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Child's self-care skills 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Adaptive Behavior Assessment System Third Edition (ABAS 3) – Self-Care subscale. A norm referenced measurement designed to assess adaptive skills. The mean and standard deviation values for healthy individuals are 10 mean and 3 SD; higher scores indicate better functioning, and lower scores indicate below-average functioning.
- Child's depressive symptoms 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System (PROMIS) Parent Proxy-Depressive Symptoms (SF6a). Short versions of PROMIS parental report paediatric measures of depression (6 items). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Child's mobility 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System PROMIS Parent Proxy-Mobility v2.0 (SF8a). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Receipt of school support programmes 1 year before the injury and 1 year after the injury. School records include information on provision of individualised education programmes, and 504 accommodation plans.

Other outcomes

- Parent's anxiety symptoms 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System PROMIS Anxiety (SF8b). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Caregiver self-efficacy 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. The Caregiver Self Efficacy (CSE) scale. 7-item scale that measures caregivers' confidence in caring and advocating for people with brain injuries.
- Navigation evaluation 12 months after discharge from the hospital. Family Experiences with Coordination of Care (FECC) measurement. A 20-item list of quality indicators of care co-ordination and engagement with patient navigators for children with medical complexity.
- Engagement with video education materials using ongoing tracking (from enrolment to 12 months' follow-up) using Google analytics
- McMaster Family Assessment Device (FAD) 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Family general functioning. A 12-item scale that evaluates communication, roles, affective response, involvement and problem-solving among families.
- Parent's depressive symptoms 1 month before injury, 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Patient-Reported Outcomes Measurement Information System PROMIS Depressive Symptoms (SF6b). Symptoms are rated on a 5-point scale and converted to standard scores. The general population mean is 50 (SD 10). Higher scores denote better outcomes.
- Caregiver Community Self Efficacy (COMSE) 24 hours before discharge from the hospital, 3 months, 6 months, and 12 months after hospital discharge. Caregiver Community Self-Efficacy

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Jimenez 2021 *(Continued)*

	(COMSE) measures caregivers' confidence in accessing community services for people with brain injuries.
Starting date	7 July 2022
Contact information	Maria A Oliva; (206)8842506; Andrea.Oliva@seattlechildrens.org
Notes	Ethics US NIH Grant R01HD103700-01A1 STUDY00003331

Lipman 2019

Study name	Integrated community health workers into the care of children with type 1 diabetes
Methods	Study design: randomised controlled trial, parallel assignment with cross-over Primary study: – Allocation: 1:1 Controlled: 'usual care' = standard diabetes care group Blinding: not to intervention Arms: ?3; usual = standard care for transition, intervention = community health worker. The support provided for this year will be tailored to the patient's needs but may include problem-solving surrounding issues related to work/education, accessing healthcare/medications, engagement with the healthcare team, transportation, housing or food insecurity. Interactions with patients will be through home visits, telephone encounters, text messaging or email. This will be added to their medical care and will be documented in the patient's medical record. Other: community health worker added to diabetes team. Dates and follow-up: April 2018 to December 2022
Participants	Inclusion criteria: age 4–18 years; type 1 diabetes mellitus > 1 year; in previous year > 2 of: diabetes-related hospital admissions and emergency department visits and missed appointments or > HbA1c 9.5% Exclusion criteria: children in care without an identified primary caregiver Recruitment: – Setting: diabetes centre at Children's Hospital of Philadelphia Location: Children's Hospital of Philadelphia
Interventions	Prerandomisation: 84 participants **Intervention**: community health worker **Control**: usual care Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcome**

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Lipman 2019 *(Continued)*

- HbA1c – improvement in glycaemic control

Secondary outcomes

- Hospital admissions
- Attended outpatient department appointments
- Missed outpatient department appointments
- Emergency department utilisation
- Primary caregiver's diabetes self-efficacy
- Quality of life of primary caregiver

Starting date	
Contact information	
Notes	Ethics: not reported. Declarations of interests/disclosures: not reported. Funding: states "Sponsored by CHOP" [Children's Hospital Philadelphia]; unsure if this means funding by Children's Hospital of Philadelphia. Trial registration or protocol registration or publication: DOI: 10.1016/j.pedn.2019.08.014.

NCT01834456

Study name	Comprehensive care of children of medical complexity
Methods	Study design: randomised controlled trial Primary study: – Allocation: 1:1 Controlled: current standard care Blinding: not to intervention Arms: 2; children's comprehensive care vs standard care Centre: Austin, Texas Dates and follow-up: 2011 to "ongoing"
Participants	Inclusion criteria: age 1. 0–17 years; autism and 1 other significant medical condition; determined to be sufficiently complex by team Exclusion criteria: cannot have primary oncological diagnosis or cystic fibrosis; has T21 and does not have significant comorbid diagnoses Recruitment: – Setting: Specially for Children, Austin, Texas Location: hospital/outpatient department
Interventions	Prerandomisation: target 450, minimum 300 **Intervention**: children's comprehensive care; child will receive primary care, including preventive care, acute care, well checks, and immunisations. If this child is hospitalised at Dell Children's

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT01834456 *(Continued)*

	Medical Center (not including day surgery procedures), a practitioner from children's comprehensive care will visit the child shortly after admission and collaborate with the hospital team to co-ordinate care at discharge. In addition, children's comprehensive care will co-ordinate and monitor all other aspects of the child's medical, dental, behavioural, and developmental care, including the development of individualised care plans that are reviewed annually or with change of medical status, and implemented and maintained by children's comprehensive care. Other changes to care delivery include access to embedded palliative, developmental, and behavioural care; use of a consultant-model for specialist care; use of telemedicine, greater use of care co-ordination and case management; and, holistic care of child and family-including psychosocial screening and referral. Children's comprehensive care will use social workers, registered nurses, case-managers, and a child life specialist to offer more holistic care co-ordination, family support, and case-management. **Control**: current standard care Co-interventions or additional treatments: none Duration of treatments and follow-up details: 3 years
Outcomes	**Primary outcome** • Change in healthcare utilisation and cost of care (emergency department visits, hospitalisations, and specialist visits) **Secondary outcomes** • Change in quality and satisfaction • Change in family impact (Paediatric Quality of Life Inventory – Family impact module) • Change in family experience using qualitative interviews
Starting date	
Contact information	
Notes	Ethics: not reported. Declarations of interests/disclosures: not reported. Funding: not reported. Trial registration or protocol registration or publication: NCT01834456.

NCT03648710

Study name	Community health workers and mHealth for sickle cell disease care
Methods	Study design: randomised controlled trial Primary study: – Allocation: 1:1 Controlled: usual care for transition to adult services Blinding: not for intervention Arms: 2; control vs community health worker + mobile health app

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT03648710 *(Continued)*

	Centre: St Christopher's Hospital for Children, Children's Hospital Medical Centre (Cincinnati), Steven and Alexandra Cohen Children's Medical Centre of Northwell Health, Connecticut Children's Medical Centre, patient-centred outcomes research institute Dates and follow-up: started January 2019; aimed to complete December 2022
Participants	Inclusion criteria: aged ≥ 17 years and appropriate for transition to adult haematology within 12 months Exclusion criteria: intellectual impairment or unable to participate meaningfully with community health worker or use mobile app
Interventions	Prerandomisation: target 450 participants **Intervention**: community health worker + mobile health app **Control**: standard care Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcomes** • Health-related quality of life • Acute care use **Secondary outcome** • Intervention treatment effects
Starting date	January 2019
Contact information	
Notes	Ethics: not specified Declarations of interests/disclosures: ? Children's Hospital Philadelphia (listed as 'sponsor' on ClinicalTrials.gov) Funding: not specified Trial registration or protocol registration or publication: NCT03648710

NCT04238949

Study name	Community health workers in pediatric patients with newly diagnosed type 1 diabetes
Methods	Study design: randomised controlled trial; parallel assignment Primary study: – Allocation: 1:1 Controlled: "usual care" (standard diabetes care group) Blinding: not to intervention Arms: ?2; usual vs community health worker Centre: Children's Hospital Philadelphia

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT04238949 *(Continued)*

	Dates and follow-up: December 2019 to January 2023
Participants	Inclusion criteria: aged < 17 years; within 31 days of type 1 diabetes mellitus diagnosis; government insurance at enrolment; live within 30 minutes of Children's Hospital Philadelphia; plans to complete 1st year of type 1 diabetes mellitus programme at Children's Hospital Philadelphia; autoantibody positive; English-speaking parent and patient Exclusion criteria: autoantibody negative; children in care with no primary caregiver; Medicare insurance; lives > 60 minutes from Children's Hospital Philadelphia Recruitment: –
Interventions	Prerandomisation: target 40 participants **Intervention**: community health worker (intervention includes social determinants of health screening and goal setting, with home visits); possibly the community health worker was added to the standard diabetes team **Control**: usual care (standard diabetes care group) Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcome** • HbA1c – improvement in glycaemic control **Secondary outcomes** • Hospital admissions • Attended outpatient department appointments • Missed outpatient department appointments • Emergency department utilisation • Primary caregiver's diabetes self-efficacy • Quality of life primary caregiver • Social determinants of health • Caregiver and participant depression • Healthcare costs
Starting date	
Contact information	
Notes	Ethics: not reported. Declarations of interests/disclosures: not reported. Funding: Children's Hospital Philadelphia, Leonard Davis Institute of Health Economics. Trial registration or protocol registration or publication: DOI: 10.1016/j.pedn.2019.08.014.

NCT05294042

Study name	Patient navigators for children's community mental health services in high poverty urban communities
Methods	Study design: interventional (clinical), parallel assignment

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05294042 *(Continued)*

	Primary study: – Allocation: randomised Controlled: yes Blinding: double (participant and care provider) Arms: 3; paraprofessional navigation vs case manager navigation condition vs wait-list as usual Centre: – Dates and follow-up: –
Participants	Inclusion criteria: aged 5–12 years; African American and Latino children; new referrals on the wait list for outpatient mental health services; have been screened and deemed appropriate for services at 1 of 2 social service participating community mental health agencies Exclusion criteria: – Recruitment: aiming for 666 participants
Interventions	Prerandomisation: target 666 participants **Intervention 1** (experimental): paraprofessional navigation (implement a model of navigation with caregivers focused on reducing logistical and attitudinal barriers to care) **Intervention 2** (active comparator): case manager navigation condition (implement a model of navigation with caregivers focused on reducing logistical and attitudinal barriers to care) **Control**: wait list as usual Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcomes** • Initiation of services by caregiver (time frame up to 18 months) • Attendance in services at 18 months; number of times attended • Change from baseline measure of perceived homophily at 6 months, 12 months, and 18 months. Measure of Perceived Homophily is a 16-item, 4-factor continuous measure of an individual's perceived similarity and dissimilarity of another individual. This measure will be used to determine how similar the caregiver perceives their navigator. The 4 dimensions include: Attitude, Background, Value, and Appearance. Each dimension includes 4 items rated 1–7 (e.g. 1 = doesn't think like me to 7 = thinks like me). Cronbach's α ranges from 0.51 to 0.93. • Change from baseline social network assessment of boundary spanning at 6 months, 12 months, and 18 months. Caregivers will be asked 2 questions at each assessment time point to determine sources of influence on services recommended by providers: 1. "Has your provider recommended services or practices to help with your child's mental health or family needs? If yes, please name them" and for each service or practice named by the caregiver, 2. Did you talk with anyone besides your provider about the service or practice? If yes, please indicate who you talked to about this service or practice. These questions will allow us to assess whether navigators are serving as a boundary spanner. At each time point, researchers will calculate the proportion of services or practices recommended by the provider that were also discussed with the navigator. • Change from Baseline Norbeck Social Support at 6 months, 12 months, and 18 months using Norbeck Social Support Questionnaire. The Norbeck Social Support Questionnaire examines multiple components of caregiver social support. The Total Network Support Subscale (3 items) is the sum of the total number of members (up to 24) parents identify in their support network, frequency of contact with each member (1 = once a year or less to 5 = daily), and length of the relationship with each member on a 5-point scale (1 = < 6 months to 5 = > 5 years). The Total Functional Support Subscale (6 items) measures the sum of perceived affective/emotional (4 items) and instrumental/tangible support (2 items; 0 = not at all to 4 = a great deal). In addition, the Norbeck So-

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05294042 *(Continued)*

cial Support Questionnaire will also be used to examine the extent to which navigators provided context-relevant social support to caregivers. Scores range from 0 (not named or named but no support) to 24 (maximum support).

- Change from Baseline Parental Attitudes Toward Psychological Services at 6 months, 12 months, and 18 months using Parental Attitudes Toward Psychological Services Inventory. This is a 26-item scale that assesses parental attitudes toward outpatient mental health services across 3 domains: help-seeking attitudes, help-seeking intentions, and mental health stigma. Items are rated from 0 (strongly disagree) to 5 (strongly agree). The Parental Attitudes Toward Psychological Services Inventory has demonstrated discriminant validity as well as adequate internal consistency (Cronbach's α ranging from 0.72 to 0.92) and test-retest reliability (Pearson r ranging from 0.66 to 0.82).
- Change from Baseline Family Empowerment at 6 months, 12 months, and 18 months. The adapted version of the original Family Empowerment Scale was designed to assess empowerment for families whose children have emotional disabilities. It consists of 34 items and 3 subscales: Family Empowerment (the ability to manage day-to-day life of the family, 12 items), Service System Empowerment (the caregiver's sense of ability to interact with the services system to obtain needed services, 12 items), and Community/Political Empowerment (the caregiver's sense of ability to advocate for improved services, 10 items). Each subscales' internal consistency is high with Cronbach's alpha coefficients ranging from 0.87 to 0.88. Test-retest reliability is also high, ranging from 0.77 to 0.85, with high alpha reliability for the adapted version (0.94).
- Change from Baseline Vanderbilt Mental Health Self Efficacy at 6 months, 12 months, and 18 months. This scale consists of 25 items measuring parents' self-efficacy beliefs and behaviour expectations about mental health treatment for their children on a 5-point scale (1 = strongly agree, 5 = strongly disagree). The questionnaire has been used with both normative and high-risk samples with high internal consistency (alpha = 0.93 for normative and high-risk samples). Construct validity has been established, with higher scores related to more parent collaboration with providers, increased social support, and more mental health service knowledge.
- Change from Baseline Barriers to Treatment Participation at 6 months, 12 months, and 18 months using the Barriers to Treatment Participation Scale. This is a 44-item scale that is administered via caregiver interview assessing barriers to participation in children's treatment. Items are rated from 1 (never a problem) to 5 (very often a problem), measuring 4 different areas: stressors or obstacles that compete with treatment, treatment demands, perceived relevance of treatment, and relationship with the therapist, with high internal consistency (Cronbach's α = 0.86).
- Change from Baseline Patient-Reported Outcomes Measurement and Information System Global Health Scale at 6 months, 12 months, and 18 months. This 10-item self-report scale was developed to evaluate individuals' perceptions of overall health status and its impact on quality of life. The scale produces 2 subscale scores: Physical Health and Mental Health. Items are reported on a Likert scale of 1 to 5, with the exception of an overall pain scale, which is rated from 1 (no pain) to 10 (worst pain). Each scale has high internal consistency (Mental Health: alpha = 0.86, Physical Health: alpha = 0.81), and high convergent validity with other measures of health-related quality of life.
- Change from Baseline OHIO Scales at 6 months, 12 months, and 18 months. The OHIO scales is a broad measure of functioning for young people aged 5–18 years. It includes 2 subscales addressing problem areas (α = 0.86) and positive areas of functioning (α = 0.91). Each subscale contains 20 items. There is a parent report and a clinician report. Study will utilise the Functioning subscale.
- Change from Baseline Strength and Difficulties at 6 months, 12 months, and 18 months using Strengths and Difficulties Questionnaire. Caregivers will complete the Strengths and Difficulties Questionnaire at baseline to derive 3 scores of child symptoms: symptom severity, externalising difficulties, and internalising difficulties. This is a 25-item screening tool for young people ages 3–17. The response scale has 3 anchors (0 = not true, 1 = somewhat true, and 2 = certainly true). Internal consistency for the parent report total difficulties score is 0.8 and inter-rater agreement is 0.44.
- Demographics at baseline. Child age, gender, and ethnicity, as well as other demographics, will be reported by the caregiver via REDCap. Caregiver demographics will be collected by research assistants via REDCap.

Secondary outcomes: –

Starting date	3 March 2022

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

NCT05294042 *(Continued)*

Contact information	Tara G Mehta; University of Illinois at Chicago Pedro L Perez Aquino MS; (312)9965155; pleopa@uic.edu
Notes	Estimated study completion 28 February 2026

Orkin 2019

Study name	Complex care for kids Ontario: a protocol for a mixed methods RCT of a population-level care coordination initiative for children with medical complexity
Methods	Study design: randomised controlled trial Allocation: 1:1 (70:70) Controlled: wait list (e.g. standard care pre-intervention) Blinding: not possible Arms: 2; wait list vs care co-ordination Dates and follow-up: questionnaires at 6 months, 12 months, and 24 months
Participants	Inclusion criteria: age < 18 years and meets tech-dependent or users of high intensity care (or both) + fragility + chronicity + complexity Exclusion criteria: high utilisation of hospital care (≥ 3 admissions, ≥ 2 paediatric intensive care unit, ≥ 30/7 of total hospital admission in last 3 months, excluding newborn admission); already followed by complex care team; parents will not be involved in care in coming 2 years; inadequate English; aged ≥ 16 years; medical status deemed highly fragile; has tracheotomy and home ventilation Baseline characteristics: age, sex, diagnosis, ethnicity, medications, medical devices, and hospitalisations. Caregiver baseline characteristics also collected – sex, education level, employment status, ethnicity, primary language. Setting: 4 tertiary children's hospitals Location: Ontario, Canada
Interventions	**Intervention**: aiming for 70 participants. Care co-ordination, including family/healthcare provider; creation and management of co-ordinated care plan between acute care, primary care, rehabilitation, home, and community care. Key worker available for advice weekdays between 9 am and 5 pm and would also develop emergency plans for out of hours. **Control**: aiming for 70 participants. Standard care (12 month wait until intervention) Duration of treatments and follow-up details: data collection at baseline, 6 months, 12 months, and 24 months. Primary analysis will be comparison for service delivery outcomes at 12 months (difference between control and intervention).
Outcomes	**Primary outcomes** • Co-ordination of care among health providers and families (Family Experiences with Care Coordination) • Co-ordination of care between health providers and families • Utility of follow-up planning tools **Secondary outcomes**

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Orkin 2019 *(Continued)*

	• Child quality of life and overall emotional health • Child physical pain • Parent quality of life • Parent perceived emotional and physical health • Parent energy and fatigue • Effect of child's condition on parent finances and ability to work • Cost-effectiveness analysis for intervention compared to standard care in reducing hospital admission
Starting date	
Contact information	
Notes	Ethics: has been obtained. Declarations of interests/disclosures: none declared. Funding: not reported. Trial registration or protocol registration or publication: NCT02928757.

Samuel 2019

Study name	Pragmatic trial evaluating the effectiveness of a patient navigator to decrease emergency room utilisation in transition age youth with chronic conditions: the Transition Navigator Trial protocol
Methods	Study design: pragmatic randomised controlled trial Primary study: – Allocation: 1:1 Controlled: usual care Blinding: not to intervention Arms: 2; usual care vs patient navigator Dates and follow-up: commenced January 2018
Participants	Inclusion criteria: aged 16–21 years; receiving care from ≥ 1 selected paediatric outpatient hospital and community clinics; have a chronic medical condition (conditions which are ≥ 3 months in duration/lifelong with multiple morbidities or multiorgan/system manifestations or conditions with typically affect a single organ/system, or combinations of these); be expected to transfer to adult speciality care in next 12 months Exclusion criteria: enroled in another transition-related study involving a navigator or similar intervention; transfer will not occur during the time interval for the study; will be moving out of Alberta during the study (e.g. going away for college) resulting in inability to report on primary outcome (emergency department visits) within the province; inability to read and write in English Recruitment: commenced January 2018 (42-month recruitment), participants recruited from 41 speciality paediatric clinics at 3 participating hospitals (Glenrose Rehabilitation Hospital, Stollery Children's Hospital, and Alberta Children's Hospital) Setting: outpatient department Location: Alberta, Canada

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Samuel 2019 *(Continued)*

Interventions	
Outcomes	**Primary outcomes** • Rate of all-cause emergency department and urgent care visits **Secondary outcomes** • Hospital inpatient care utilisation measures and ambulatory care utilisation measures – rate of events • Transition Readiness Questionnaire and participant-reported health status • Costs of patient navigator
Starting date	
Contact information	
Notes	Ethics: obtained from the University of Calgary Conjoint Health Research Ethics Board (REB #162561) and the University of Alberta Health Research Ethics Board (Pro00077325). Research team composed of diverse stakeholders who are committed to improving transition of care who will assist with dissemination of results. Declarations of interests/disclosures: Alberta Health Services (Research Number 1040209), Alberta Children's Hospital Foundation (Research Number 1042146), Stollery Children's Hospital Foundation, Canadian Institutes of Health Research (388256-CHI-CBBA-161557). Funding: none declared. Trial registration or protocol registration or publication: NCT03342495.

Smaldone 2019

Study name	HABIT efficacy and sustainability trial, a multi-center randomized controlled trial to improve hydroxyurea adherence in youth with sickle cell disease: a study protocol
Methods	Study design: randomised controlled trial Primary study: – Allocation: 1:1 Controlled: usual care + education handouts Blinding: not for intervention Arms: 2; standard care vs community health worker Centre: Columbia University Irving Medical Center (CUIMC), New York; Montefiore Hospital, Bronx, New York; Cohen Children's-Northwell Health, Queens New York; Children's Hospital of Philadelphia, Philadelphia, Pennsylvania Dates and follow-up: from September 2018, 12-month study
Participants	Inclusion criteria: aged 10–18 years; diagnosed with sickle cell disease type HbSS or HbS-B0 thalassaemia; has been prescribed hydroxyurea for a minimum of 18 months; current hydroxyurea dose is within 5% of dose at personal best haemoglobin F, and has been stable for the preceding 3 months; pre-enrolment haemoglobin F is ≥ 15% below the personal best value based on the calculated mean of 2 haemoglobin F assessments over the preceding 12 months; is able to use a mobile phone with text message capability; can speak and read either English or Spanish; parents are eligi-

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Smaldone 2019 *(Continued)*

	ble for the study if the youth meets all inclusion criteria and if parent can speak English or Spanish; is willing to participate in clinic and community health worker study visits; the family expects to reside in their present community for the next 1.5 years; haemoglobin F ≥ 15% below the youth's personal best value at month 0 study visit Exclusion criteria: youth aged < 10 years or > 18 years; not prescribed hydroxyurea; had < 2 assessments of haemoglobin F level over the past year; has had a blood transfusion within 3 months preceding enrolment; if the youth does not currently reside with the parent or legal guardian; is a sibling of a youth enroled in the study; has cognitive impairment of > 2 grade levels below what is expected for age; female youth if sexually active and not using a form of contraception due to hydroxyurea's teratogenic risk to the fetus or are pregnant; parents are excluded from study participation if he/she is not the primary caregiver or if the youth is in foster care Recruitment: 104 child–parent dyads
Interventions	Prerandomisation: target 104 **Intervention**: community health worker **Control**: standard care Co-interventions or additional treatments: – Duration of treatments and follow-up details: –
Outcomes	**Primary outcome** • Hydroxyurea adherence by measurement of progress to haemoglobin F to their individualised personal best target level, and increased proportion of days covered by hydroxyurea (pharmacy records) **Secondary outcomes** • Youth health-related quality of life • Self-management responsibility concordance • Acute hospital use • Self-reported disease symptoms
Starting date	
Contact information	
Notes	Ethics: institutional review boards at all 4 sites have approved study protocols. Eligible parent–youth dyads willing to participate will sign a written consent or assent (or both). Declaration of interests/disclosures: none. Trial status: ongoing. Funding: NIH, NINR (R01:NR017206 to NSG and SA). Supported by P30 NR016587 (to Bakken and AS) and a Clinical-Translational Science award from NCATS (UL1 TR001873 to Riley). Funders had no role in study design, collection, analysis, and interpretation of data, or in writing the manuscript. Trial registration or protocol registration or publication: NCT03462511.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

van Zwieten 2019

Study name	NAVKIDS2 trial: a protocol for a multi-centre, staggered RCT of a PN [patient navigator] intervention in children with chronic disease
Methods	Study design: multicentre, staggered entry, wait list randomised controlled trial Primary study: – Allocation: 1:1 Controlled: delayed entry to intervention will serve as control Blinding: unable for intervention Arms: 2, cross-over Centre: 5 centres in Australia: Children's Hospital Westmead, Sydney Kids Randwick, QCH, RCH Melbourne, Women's and Children's Adelaide Dates and follow-up: recruitment end 2019/early 2020
Participants	Inclusion criteria: chronic kidney disease 1–5, chronic kidney disease on dialysis, or chronic kidney disease with kidney transplant; aged 0–17 years; low socioeconomic background (weekly household income < 1250 Australian dollars, poor or very poor self-perceived financial status, single parent on social benefits, both parent unemployed, families in public housing, living in rural/remote areas); caregiver can speak English, or have a family member who can speak English Exclusion criteria: life expectancy < 12 months; unable or unwilling to provide consent by caregiver (and child assent if child is ≥ 16 years) Recruitment: many from Kids with Chronic Kidney Disease study but also any patients fulfilling the inclusion criteria from each department.
Interventions	Prerandomisation: target 150–168
Outcomes	**Primary outcome** • Self-rated health of child 6 months after intervention (participant-reported health outcome) for children aged > 8 years, parent-rated health of child 3–7 years **Secondary outcomes** • Mean difference in self-rated health of child and caregiver • Utility-based quality of life estimates • Mortality • Healthcare costs • Progression of kidney dysfunction (estimated glomerular filtration rate) and other biomarkers • Caregiver's satisfaction of healthcare • Missed school days • Intervention cost-effectiveness • Intervention satisfaction, barriers, enablers, fidelity • Hospitalisations
Starting date	
Contact information	
Notes	Ethics: obtained from the Sydney Children's Hospital Network Human Research Ethics Committee (approval number: HREC/18/SCHN/325). Informed and voluntary written consent will be obtained from all participating caregivers (and assent from participating children where appropriate to their age), as detailed in the 'consent process' section.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

van Zwieten 2019 *(Continued)*

	Funding: National Health and Medical Research Council (NHMRC) Medical Research Future Funds grant (APP 1170021) AvZ and SC receive funding from NHMRC postgraduate scholarships (AvZ APP1115259 and SC APP1168994). GW and AT are recipients of NHMRC Career Development Fellowships (GW APP1147657 and AT APP1106716). MH and ATP receive support from a NHMRC Program Grant (APP1092957). The funding organisations will have no involvement in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or the decision to submit the manuscript for publication. Declaration of interests/disclosures: 1 researcher (RW) is the Program Director of CanCare, a patient navigation programme for people with cancer run by the Prostate and Breast Cancer Foundation, Australia. All authors declare that they have no competing interests. Trial registration or protocol registration or publication: co-ordinated by Australasian Kidney Trials Network (AKTN). Data Safety monitoring board (DSMB) for monitoring adverse events and will ensure safety of children and families. Prospectively registered (12 July 2018; ACTRN12618001152213).

Wahi 2022

Study name	Screening and addressing social needs of children and families enroled in a pediatric weight management program: a protocol for a pilot randomized controlled trial
Methods	Study design: parallel randomised controlled trial Primary study: pilot (unpublished) Allocation: 1:1 Controlled: yes Blinding: yes Arms: 2 Centre: single Dates and follow-up: –
Participants	Inclusion criteria: enroled < 18 months in the CENC Growing Healthy Weight Management Clinic; child age 2–18 years Exclusion criteria: child in the care of child protection services or living in group or foster care (or both) as children in these settings will not be living within typical family systems to have social needs addressed by this intervention; parent/guardians who cannot read and write in English; if a family was enroled with 1 child and a subsequent child joins the clinic, the family is not eligible to re-enrol into the study Location: McMaster Children's Hospital
Interventions	Prerandomisation: target 40 participants **Intervention**: community navigator. Include an in-person, telephone call, or videoconference visit (determined by participant preference) with a community navigator to help connect with appropriate services for their specific needs and geographic region of residence. Referrals will be sourced using the www.211ontario.ca website and tools as well as a regional services resource guide developed by the study team. The intervention will include bimonthly check-ins in person during clinic by telephone, email, or videoconference. **Control**: given a paper or emailed an electronic copy of community resources and services. If there are any concerns from the social needs assessment tool, the research assistant will bring them to

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Wahi 2022 *(Continued)*

	the attention of the principal investigator who will discuss it with the clinical team to decide on the appropriate action to be taken. Co-interventions or additional treatments: all families who consent to participate in the study will complete the social needs assessment tool. Those who do not screen positive in any area of social need will not be randomised but will be included in the study for the purpose of comparison and will have follow-up data collected at 6 months. Duration of treatments and follow-up details: intervention points 2 weeks, 2 months, and 4 months after allocation. Final at 6 months.
Outcomes	**Primary outcomes** • Recruitment rates: recruitment will be successful if 80% of our target sample is met in the 6 months of recruitment • Uptake of intervention: will be considered successful if >80% of families complete the intervention • Follow-up of participants: will be considered successful if > 90% of families complete all the study visits **Secondary outcomes** • Change in body mass index z-score be calculated using World Health Organization growth charts, for age and sex. Height and weight of the child will be collected from the chart at baseline and at the end of the intervention. Body mass index will be calculated by dividing weight in kilograms by the square of the body height in metres squared • Change in body composition: body fat will be assessed at baseline and at the end of the intervention using the Quantum II BIA analyzer (RJL Systems). Bioelectrical impedance analysis is non-invasive and portable • Change in quality of life. Both the participant and the parent or guardian will be asked to complete the Paediatric Quality of Life Inventory
Starting date	25 January 2021
Contact information	Gita Wahi; (905)5212100; wahig@mcmaster.ca
Notes	

HbA1c: glycated haemoglobin.

DATA AND ANALYSES

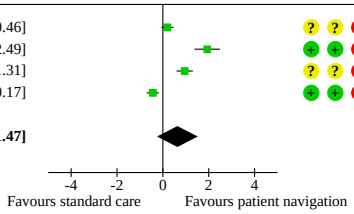
Comparison 1. Child/adolescent quality of life

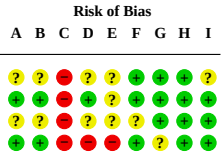
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Child/adolescent quality of life between baseline and 12 months (self-reported)	4	671	Std. Mean Difference (IV, Random, 95% CI)	0.63 [-0.20, 1.47]
1.2 Child/adolescent quality of life between baseline and 12 months (parent proxy-reported)	2	309	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-2.21, 2.40]

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Analysis 1.1. Comparison 1: Child/adolescent quality of life, Outcome 1: Child/adolescent quality of life between baseline and 12 months (self-reported)

Study or Subgroup	Patient navigation Mean	SD	Total	Standard care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Flores 2009	10	4.95	112	9	5.1	108	25.6%	0.20 [-0.07 , 0.46]
Frakking 2022	14.9	3.46	41	7.8	3.84	34	23.6%	1.93 [1.38 , 2.49]
Katz 2014	2.17	1.38	102	0.5	2.31	51	25.1%	0.95 [0.60 , 1.31]
Weinstein 2021	0.1	1.7	108	0.8	1.5	115	25.6%	-0.44 [-0.70 , -0.17]
Total (Wald{fn})			**363**			**308**	**100.0%**	**0.63 [-0.20 , 1.47]**



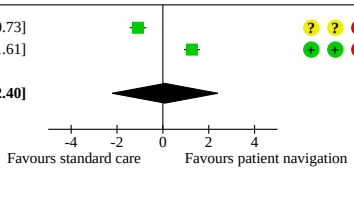


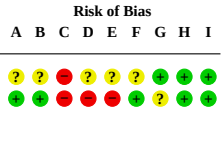
Test for overall effect: Z = 1.49 (P = 0.14)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 0.69; Chi² = 76.26, df = 3 (P < 0.00001); I² = 96%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Baseline outcomes measurement
(H) Baseline characteristics
(I) Other bias

Analysis 1.2. Comparison 1: Child/adolescent quality of life, Outcome 2: Child/adolescent quality of life between baseline and 12 months (parent proxy-reported)

Study or Subgroup	Patient navigation Mean	SD	Total	Standard care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Katz 2014	0.48	2.1	102	3.2	3.15	51	50.0%	-1.08 [-1.44 , -0.73]
Weinstein 2021	4.2	1.16	77	2.6	1.34	79	50.0%	1.27 [0.92 , 1.61]
Total (Wald{fn})			**179**			**130**	**100.0%**	**0.09 [-2.21 , 2.40]**





Test for overall effect: Z = 0.08 (P = 0.94)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 2.74; Chi² = 86.12, df = 1 (P < 0.00001); I² = 99%

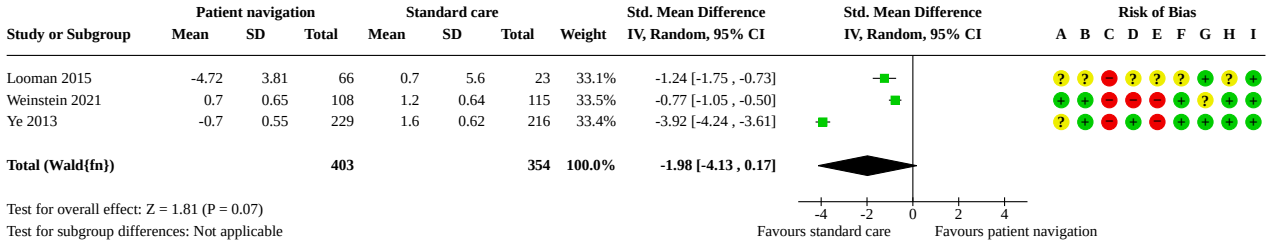
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Baseline outcomes measurement
(H) Baseline characteristics
(I) Other bias

Comparison 2. Parent quality of life

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Parent quality of life between baseline and 24 months	3	757	Std. Mean Difference (IV, Random, 95% CI)	-1.98 [-4.13, 0.17]

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Analysis 2.1. Comparison 2: Parent quality of life, Outcome 1: Parent quality of life between baseline and 24 months



Study or Subgroup	Patient navigation Mean	SD	Total	Standard care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Looman 2015	-4.72	3.81	66	0.7	5.6	23	33.1%	-1.24 [-1.75 , -0.73]
Weinstein 2021	0.7	0.65	108	1.2	0.64	115	33.5%	-0.77 [-1.05 , -0.50]
Ye 2013	-0.7	0.55	229	1.6	0.62	216	33.4%	-3.92 [-4.24 , -3.61]
Total (Wald{fn})			**403**			**354**	**100.0%**	**-1.98 [-4.13 , 0.17]**

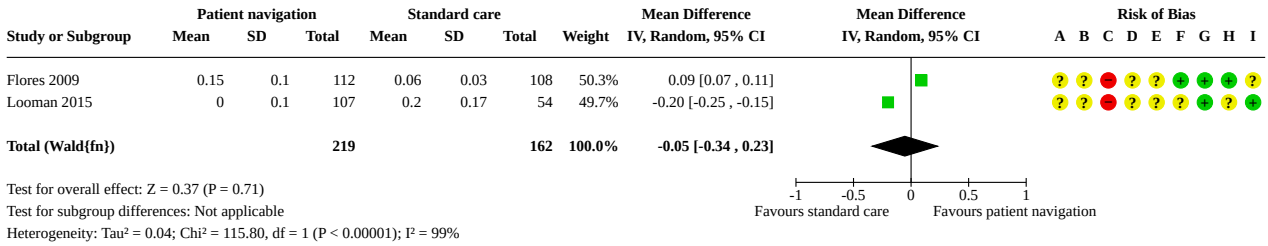
Test for overall effect: Z = 1.81 (P = 0.07)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 3.57; Chi² = 226.49, df = 2 (P < 0.00001); I² = 99%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Baseline outcomes measurement
(H) Baseline characteristics
(I) Other bias

Comparison 3. Hospitalisation rates

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Hospitalisation rates between baseline and 12 months	2	381	Mean Difference (IV, Random, 95% CI)	-0.05 [-0.34, 0.23]

Analysis 3.1. Comparison 3: Hospitalisation rates, Outcome 1: Hospitalisation rates between baseline and 12 months



Study or Subgroup	Patient navigation Mean	SD	Total	Standard care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Flores 2009	0.15	0.1	112	0.06	0.03	108	50.3%	0.09 [0.07 , 0.11]
Looman 2015	0	0.1	107	0.2	0.17	54	49.7%	-0.20 [-0.25 , -0.15]
Total (Wald{fn})			**219**			**162**	**100.0%**	**-0.05 [-0.34 , 0.23]**

Test for overall effect: Z = 0.37 (P = 0.71)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 0.04; Chi² = 115.80, df = 1 (P < 0.00001); I² = 99%

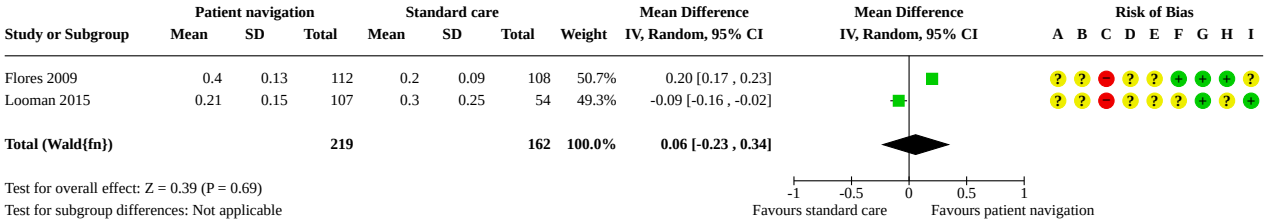
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Baseline outcomes measurement
(H) Baseline characteristics
(I) Other bias

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Comparison 4. Rates of emergency department attendance

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Rates of emergency department attendance between baseline and 12 months	2	381	Mean Difference (IV, Random, 95% CI)	0.06 [-0.23, 0.34]

Analysis 4.1. Comparison 4: Rates of emergency department attendance, Outcome 1: Rates of emergency department attendance between baseline and 12 months



Test for overall effect: Z = 0.39 (P = 0.69)
Test for subgroup differences: Not applicable
Heterogeneity: Tau² = 0.04; Chi² = 52.77, df = 1 (P < 0.00001); I² = 98%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Baseline outcomes measurement
(H) Baseline characteristics
(I) Other bias

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ADDITIONAL TABLES

Table 1. Description of patient navigator interventions for each study

Study	Number (intervention group)	Target patient population	Training of patient navigator	Activities/assistance provided	Duration of intervention	Frequency of intervention	Location of intervention	Focus of intervention	Attrition
Flores 2009	112	African American or Latino, aged 2–18 years, asthma diagnosis, lived in Milwaukee	2.5-day training session led by a nurse asthma specialist and programme co-ordinator. 73-page manual in English and Spanish. Resources on insurance programmes for uninsured children, locations of free clinics, medication and equipment teaching sheets, and creating reminder calendars for health care provider appointments. Resource manuals on assisting families with unmet needs for health insurance, housing, food, and other social concerns. Before and after test. Monthly meetings with study nurse to discuss issues.	Community meetings for asthma education, meals, opportunities for children and families to interact socially, and social networking and support. Available by telephone support. On 1st home visit and on subsequent contacts, reviewed topics of 1. why asthma is an important issue, 2. sharing experiences on caring for a child with asthma, 3. keeping children with asthma out of hospitals, 4. details regarding patient navigator intervention and study, asthma basics, asthma medication and triggers, regular and follow-up appointments, cultural issues that affect asthma care.	12 months	Monthly community meetings, monthly telephone reviews, home visit within 3 days, and 6 months after initial emergency department visit	Community learning centre, Boys and Girls Club, church or family resource centre, telephone calls, home	Health literacy, symptom reduction, financial/social assistance, care co-ordination	45 (40%) dropped out of intervention group, 44 (41%) dropped out of control group. 85 (76%) low participation (attended < 25% of meetings and completed < 50% of telephone contacts)
Frakking 2022	42	Aged 0–16 years, chronic	No specific training. Allied Health Liaison Officer	1. ascertained priorities in health care access in hospital, education, primary care, and	6 months	4 episodes,	General practitioner review	Care co-ordination,	6-week appointment: 41 (97.6%); 3 months:

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

		medical condition	was a speech pathologist with clinical experience in the multidisciplinary team assessment and intervention of paediatric neurodevelopmental conditions.	community sectors, 2. co-ordination of multidisciplinary team meetings in primary care and education, 3. assistance with health literacy and advocacy, 4. co-ordination of healthcare appointment scheduling		1 week, 3 months, 6 months mandatory		health literacy	11 (26.2%); 6 months: 9 (21.4%). Advocacy for referral acceptance by community agencies and ongoing management was the most common family-initiated request for assistance at 3 months (26 (61.9%)) and 6 months (18 (42.9%)). Assistance with co-ordination of medical and allied health appointments across hospital and community facilities was the most common family-initiated request at 12 months after diagnosis (19 children, 46.3%).
Frantatoni 2022	150	Custodial parents of neonatal intensive care unit infant, lived in Washington metropolitan area	Patient navigators were parents of infants who graduated neonatal intensive care unit > 2 years prior. 8 patient navigators trained using a programme based on Pediatric Practice Enhancement Project of the Rhode Island	1. Formal needs assessment assessed and recognised emotional, financial and social needs of families; 2. helped empower families to advocate for their child; 3. scheduled appointments and accompanied parents to them; 4. assisted with finding resources for housing, insurance, financial issues, employment, and support groups for specific disease entities; 5. provided bereavement support if needed.	12 months	1 face-to-face before discharge, monthly contact, extra contacts as needed by parent.	Neonatal intensive care unit, telephone calls or email.	Health promotion, symptom reduction, financial/social assistance, care co-ordination.	1/150 in the intervention group did not receive the intervention, 2/150 in the control group did not receive the allocated control. 88%, 90%, 85%, and 84% of all eligible participants fully completed their surveys at the 1-week, 1-month, 3-month,

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

			Parent Information Network. Had a manual of operations that served as a resource manual and allowed for consistency of care between patient navigators. Training over 3 months. Teaching methods included prereading, small group teaching, video review, group discussion, in-situ visit, role playing online teaching, peer mentorship, on-the-job training.						and 6-month intervals, respectively.
Gorelick 2006	118	Aged 2–18 years, treated for asthma, Milwaukee	No specific training. Case manager was a nurse or social worker based at a home health agency, a medical centre, or the health department, based on insurance coverage.	Performed standardised asthma needs assessments and environmental and smoking assessments, identified and addressed family asthma goals using a personalised care plan, provided asthma education by using the Fight Asthma Milwaukee Allies tool kit and additional materials, made referrals to community and other services as appropriate.	6 months	Monthly home visits	Home visits, telephone calls	Health literacy, care co-ordination	Overall, 78% of participants completed follow-up. 77 participants lost to follow-up or excluded from analysis. Intervention group: 37 (31%) lost to follow-up.
Howe 2005	21	Aged 1–16 years, T1DM ≥ 1 year, HbA1c ≥ 8.5% 2 consecutive times	No specific training. Case manager was a masters-prepared nurse who was a member of the diabetes centre	Reviewed blood sugar testing, record keeping, insulin administration, use of sliding scales, exercise management, sick-day management, and carbohydrate counting. Written guidelines given for insulin doses for hyperglycaemia and for varying	6 months	Weekly for 3 months, fortnightly for 3 months	1 education session, telephone calls	Health literacy, symptom reduction, care co-ordination	14 participants failed to complete study protocol (16%). 1 participant requested to leave the study. Remainder lost to

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

			where the study was conducted.	carbohydrate loads. Reviewed blood sugars, safety issues related to hypoglycaemia and hyperglycaemia, problem-solving skills, diet and meal planning, changing insulin dose. Discussed parenting and behaviour management skills. Communicated and collaborated with the child's primary team on developments or changes in the child's diabetes care and life issues.					follow-up. Due to no-shows at clinic, the 3-month interval times stretched to 4- to 6-month intervals.
Karnick 2007	68/70	Aged 1–16 years, asthma diagnosis	No specific training. Case manager was a nurse practitioner. A health educator carried out the education part of the case management plan	Education session once (but also provided for control group), initial case management evaluation, worked collaboratively with the family to identify problems and needs and to devise a solution action plan. The health educator supported the family in carrying out the case management plan. Health educator called families monthly to reinforce education. Participants had direct access to the health educator.	9 months	Monthly telephone calls	1 education session (all groups received this), telephone calls	Health literacy, symptom reduction, care co-ordination	Overall, of the 212 participants, 165 (77.8%) completed 9-month follow-up. Analysis available to 54/68 (79%) of group 2 (education, reinforcement) and 56/70 (80%) of group 3 (education, reinforcement, case management).
Katz 2014	52/50	Aged 8–16 years, T1DM ≥ 6 months	Research assistant with 4-year college degree, no medical background. Training in study protocol implementation and care co-ordination.	Role included outreach to families to schedule clinic appointments or to relay family concerns to medical providers. Delivered psychoeducational intervention, consisting of 30-minute session with participants and their parent/guardian on the day of a regularly scheduled, quarterly clinic visit. Psychoeducational materials related to family management of diabetes. Facilitated problem-solving exercises and role playing of realistic expectations for family	2 years	Care ambassador (intervention group 1) monthly telephone or emails, quarterly diabetes care, and care co-ordination. Care ambassador + psychoeducation	Clinical visits, telephone calls	Health literacy, care co-ordination, symptom reduction	No apparent loss to follow-up for this group. Clinic visits (intervention points) were equal for all 3 groups including control: 9.6 (SD 1.1), care ambassador: 9.0 (SD 1.7), and care ambassador + psychoeducation: 9.4 (SD 1.5) visits. No mention of adherence to

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

				teamwork. Sessions were taped and reviewed by senior study staff. Topics included 1. family teamwork and communication; 2. avoiding perfectionism and setting realistic goals; 3. blood sugar monitoring and HbA1c; 4. avoiding conflict related to diabetes; 5. weight gain and hypoglycaemia awareness; 6. decreasing feelings of burnout and isolation; 7. sessions in review; 8. research and technology update.		(intervention group 2) quarterly. Control group also received care co-ordination in the form of scheduling clinic visits.			telephone calls or email.
Laffel 1998	89	Aged 10–15 years, T1DM diagnosis	College graduates, no formal medical education, provided no prescriptive advice.	1. Assisted with appointment scheduling and confirmation; 2. helped with questions concerning billing or insurance by directing families to the appropriate personnel; 3. monitored clinic attendance of intervention participants and provide telephone or written outreach to families after missed or cancelled appointments.	2 years	Not specifically mentioned in paper	Telephone calls	Care co-ordination, financial/social assistance	2/89 lost to follow-up in clinic, 7/82 were lost to follow-up in clinic.
Looman 2015	54/54	Aged 2–15 years, 4 or more of 5 common health consequences[a] due to a health condition ≥ 12 months	Patient navigators were advanced practice registered nurses. No specific training mentioned for this.	Each advanced practice registered nurse had a maximum caseload of 105 families. Families had access to advanced practice registered nurse care co-ordinator full time during business hours. Families in the video group received a netbook with webcam, and high-speed internet service to the home was covered by the project. Advanced practice registered nurse was available during the child's clinic visits as needed, and connected with some children and families during acute hospitalisations. Encounters could be initiated by family or	2 years	Not specifically mentioned in the paper	Clinical visits, telephone calls, admissions	Care co-ordination	7/108 in the intervention groups withdrew from the study, 8/47 in the control group withdrew from the study. Analysis was limited to 66 in the intervention group and 23 in the control group due to missing data and > 180 days return of baseline survey answers.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

				advanced practice registered nurses. Activities included: 1. developing and maintaining individualised care plans with families; 2. connecting families with community resources to implement the plan of care; 3. promoting information exchange with community agencies, schools, and healthcare providers; 4. communicating with families regarding diagnostic and laboratory results; and 5. identifying the need for and initiating appropriate referrals to other healthcare providers or community services as appropriate.					
Parikh 2021	16	Aged 5–12 years, admitted with asthma exacerbation, lived in Washington, DC	Certified asthma educator recruited as a patient navigator, with prior knowledge of asthma pathophysiology, medications, resources to support the family	5 components: 1. established process with local in-house pharmacy to ensure that patients had medication in-hand for discharge; 2. emailed communication with primary care provider to share information about the programme and asthma action plan; 3. resolved questions and problems with asthma care after discharge; 4. worked with local hospital pharmacy to mail medications directly to school nurse with the necessary paperwork for in-school administration; 5. connected caregivers with an established public health organisation that does home evaluations and makes recommendations for improvements to minimise asthma trigger risks for participants.	6 months	Within 3 days, 2 weeks, then monthly for 6 months	Telephone calls	Health literacy, care co-ordination, symptom reduction	100% medications on hand at discharge, school-based asthma therapy for controller medication initiated 100%, home visit referrals made 100%, home visits completed within 4 weeks of discharge 44%, primary care provider communication 100%, patient navigator communication 81.3% at 3 days, and 46.7% at 14 days. End of study interviews: 50% (8/16) caregivers completed. 87.5% of families contin-

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

									ued school-based asthma therapy.
Seid 2010	81/84	Aged 2–14 years, asthma diagnosis.	Bachelor's level asthma home visitors trained along NHLBI guidelines (National Asthma Education and Prevention Program, 1997). Problem-solving skills training (PST) intervention based on D'Zurilla's conceptualisation (D'Zurilla 1971), adapted from a comprehensive protocol used in a previous trial of problem-solving skills training in mothers of children with cancer. 2 weeks of training, including didactiv instruction, role-playing, shadowing an experienced interventionist. Weekly supervision designed to prevent interventionist drift. Standardised via training manuals, standard materials, and behavioural checklists denoting specific pre-	1. Structured educational interventions (English or Spanish); 2. referred to existing health insurance enrolment assistance, smoking cessation, and other community support services; 3. communicated with primary care provider.	5–6 weeks	Care coordination (intervention group 1) 5 weekly sessions, care co-ordination + problem-solving training (intervention group 2) 5 weekly sessions plus 6 weekly sessions of problem-solving training carried out by health educator.	Not specified	Health literacy, care insurance, financial/social assistance, care co-ordination	Of care co-ordination (intervention group 1), 78/81 received, T2 complete 71/81, T3 complete 65/81, analysed 72. Of care co-ordination + problem-solving skill training (intervention group 2), 78/84 received, T2 complete 60/84, T3 complete 57/84, analysed 65. T2 = 3 months postintervention, T3 = 9 months postintervention.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

			scribed intervention behaviours.						
Smaldone 2018	18	Aged 10–18 years, sickle cell anaemia diagnosis	4-day training session, structured training curriculum. 2 days on roles and responsibilities, engagement with families, and role boundaries. 2 days of project-specific training, to include study goals, rationale and approach, schedule and goal of each visit, information about sickle cell anaemia disease and hydroxyurea.	1. Reviewed handouts, educational support; 2. assessed barriers to hydroxyurea; 2. observed communication and relationship with healthcare provider.	6 months	5 visits (including a month 2 clinic visit), then daily text messages with weekly contact, booster visit at 9 months	Home visits, telephone calls, text, local community-based organisation, coffee shop or quiet area within clinical space. Clinic visit for 3rd visit (month 2)	Health literacy, symptom reduction, care co-ordination	10.7% attrition (2/18 lost to follow-up due to youth illicit drug activity, study procedures too burdensome, 1/10 lost to follow-up due to incarceration).
Spaic 2019	104	Aged 17–20 years, T1DM for ≥ 1 year	No mention of formal training	Transition co-ordinators were certified diabetes educators who provided transitional education and clinical support. 1. Assisted during visits; 2. maintained contact between visits by telephone, text, or email; 3. facilitated support for insulin adjustments and sick day/hypoglycaemia management during regular hours; 4. reminded and rescheduled appointments; 5. assessed needs and facilitated referrals to other services, e.g. psychology, social work, nurse educator, dietitian; 6. provided transition-related education and material, including written instructions and maps to navigate adult diabetes centres.	18 months	8 clinic visits in 18 months, 3 paediatric, 3 adult and 2 at 12-month follow-up	Clinic visits, telephone calls	Health literacy, symptom reduction, care co-ordination, transition care	No mention of attrition rates, all recruited participants and controls included in analysis.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

Svoren 2003	94/97	Aged 7–16 years, T1DM for ≥ 6 months	College graduates, no formal medical education; however, 'trained' by research staff. (no mention of what specific training is).	Care ambassador – receive ambulatory diabetes as prescribed by participant's usual diabetes healthcare team. Assisted patients with appointment scheduling, questions regarding billing/insurance, monitor attendance at clinic.	24 months	Care ambassador (intervention group 1), 5–10 minutes per clinic visit. Care ambassador + psycho-education (intervention group 2), as above plus 8 intervention education modules (15–30 minutes per visit)	Outpatient clinics	Health literacy, care co-ordination, financial/social assistance	1/95 in the care ambassador group and 1/98 in the care ambassador + psycho-education intervention discontinued study participation and excluded from analysis. Follow-up HbA1c data available for 285/299 participants. 7/108 standard care participants had 1 baseline HbA1c data, 1/94 care ambassador participants had only 1 baseline HbA1c data, and 4/97 care ambassador + psycho-education participants had only 1 baseline HbA1c data.
Weinstein 2021	110	Aged 5–16 years, asthma diagnosis	Comprehensive asthma community health worker training curriculum conducted in phases. Phase 1: 18 hours of training of asthma basics, self-management. Phase 2: training to familiarise themselves with study protocol, Erie policies, home visitation	Asthma topics. Parent and child well-being including behavioural health discussions and referrals. Community health referrals. Social support. Environmental/trigger rearrangement.	12 months, mean duration of community health worker visit was 65.1 minutes.	Median of 7 (interquartile range 4, full range 0–17)	In patient homes (95.2%), clinics, schools, homes of family/friends	Health literacy, symptom reduction, care co-ordination, financial/social support	6 families (5.6%) refused all health worker visits, 9% 1–3 visits, 21% 4–6 visits, 55% 7–9 visits, 9% ≥ 10 visits. Visit distribution not equal by size. 56.5% of families, health worker and families felt they had achieved all their predetermined asthma goals. This

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

			strategies and documentation. Medications and trigger remediation reinforced through role-play and practical exercises. Attended a course on emergency mental health and basic training in motivational interviewing. Shadowed other health workers and Erie clinicians to gain additional asthma education skills.						influenced the number of visits some families received since visits stopped when all goals were met.
White 2017	60	Aged 17–19 years, T1DM[a] diagnosis	No specific training mentioned. Appointment/case manager for trial was designated from administrative staff member or diabetes nurse specialist from each relevant adult referral centre.	Case manager provided all information appointments allocated to the participants (appointment management). Personalised transition schedule detailing info of relevant adult clinic (location, contact info to confirm/reschedule appointments, diabetes team contact details), given a memory card with all personal medical data (transition referral letter, clinic letters, recent laboratory test results, etc.) and an information pack containing diabetes information and advice. Appointment manager acted as point of contact between intervention group and relevant adult clinic. Provided telephone reminders for 1 week and 48 hours by SMS. If appointments missed, automatic rebooking. If participants did not attend multiple appoint-	24 months	Not specifically mentioned in paper.	Community, telephone calls	Transition care, care co-ordination	11/60 withdrew from intervention group in 1st year, 5/60 withdrew from standard care in 1st year. 10/49 from intervention group had < 2 years of follow-up data, 7/49 withdrew in 2nd year of study. 10/55 had < 2 years of data from standard care group. 8/55 withdrew in 2nd year.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Table 1. Description of patient navigator interventions for each study *(Continued)*

				ments, contact was made by appointment manager. Did not provide medical advice or support; patients advised to contact medical team.					
Ye 2013	229	Children with any of these medical conditions[b]	Trained service co-ordinator followed up with the family (no further mention of what training was undertaken).	In working with the parents, an individual team of service providers was formed according to the child's health and social needs. For example, a team comprising an augmentative communication services consultant, early interventionist, occupational therapist, physiotherapist, speech and language therapist, and service co-ordinator was assembled for a child with cerebral palsy. This integrative team together with family members developed a single plan of care for the child. The service co-ordinator organised the delivery of services according to the plan. The team met with the family for ongoing assessment and revision of the plan on a regular basis.	2 years	Not specifically mentioned in paper.	Clinical visits, community	Care co-ordination	Significant rates of lost to follow-up (64 from intervention group, 57 from standard care group). Furthermore, in intervention group (229), 118 children did NOT receive treatment as 58 declined co-ordination services, 53 could not access services (not available in their local area), and 7 had ongoing integration.

T1DM: type 1 diabetes mellitus.

[a] 4 of: need for prescription medication, need for medical care, functional limitation, need for special therapies for ≥ 12 months, need or use of mental health counselling (this criteria was the optional criteria).

[b] Cerebral palsy, brain injury, developmental difficulties, Down's syndrome, spina bifida, autism, physical disability, developmental disability, pervasive developmental disorder, or chronic medical condition.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

APPENDICES

Appendix 1. Search strategies 2020 and 2023

The Cochrane Library (Wiley) Issue 7/2021

Search date: 5 May 2020, 20 January 2023

No.	Search terms
1	[mh "chronic disease"]
2	((complex* or chronic* or rare or severe) near/2 (disease? or ill* or need? or problem? or condition?)):ti,ab
3	[mh "transition to adult care"}
4	[mh “diabetes mellitus, type 1”]
5	diabet*:ti,ab
6	[mh “asthma”]
7	asthma*:ti,ab
8	[mh “cystic fibrosis”]
9	“cystic fibrosis”:ti,ab
10	[mh “pediatric obesity”] or [mh “obesity”] or [mh “overweight”]
11	(obese or obesit* or “over weight” or overweight):ti,ab
12	"cerebral palsy":ti,ab
13	[mh "cerebral palsy"]
14	[mh "anemia, sickle cell"]
15	"sickle cell":ti,ab
16	[mh "neoplasms"]
17	(neoplasm? or cancer?):ti,ab
18	{or 1-17}
19	[mh "adolescent"]
20	[mh "child"]
21	[mh "infant"]
22	[mh "child health services"]

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

23	[mh "adolescent health services"]
24	(adolescen* or babies or baby or boy? or boyhood or girlhood or child* or girl? or infan* or juvenil* or kid? or minors or minors* or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or puber* or pubescen* or school* or teen* or toddler? or underage? or under-age? or youth*):ti,ab
25	(pediatric* or paediatric* or infan* or child* or adolescen* or young):so
26	(parent? or mother? or father? or family or families or carer?):ti,ab
27	{or 19-26}
28	[mh "case managers"]
29	[mh "case management"]
30	[mh "patient navigation"]
31	[mh "patient-centered care"]
32	[mh "transitional care"]
33	[mh "mentors"]
34	[mh "community health workers"]
35	[mh "patient advocacy"]
36	((health* or patient*) next advoca*):ti,ab
37	(community next health next worker?):ti,ab
38	((case next manager?) or (care next manager?)):ti,ab
39	((patient or care or healthcare or service? or communit* or system? or personal) near/3 navigat*):ti,ab
40	((care or healthcare or management) near/2 (coordinat* or co-ordinat*)):ti,ab
41	(team* near/2 (care or healthcare or treat* or assess* or consult* or program* or intervention?)):ti,ab
42	((integrat* or coordinat* or co-ordinat* or collaborat* or cooperat* or co-operat*) near/2 (care or healthcare or intervention? or program* or service? or system?)):ti,ab
43	(communit* and navigat*):ti,ab
44	((care or healthcare) near/2 ambassador?):ti,ab
45	((parent? or healthcare or care or mother? or father?) near/3 mentor?):ti,ab
46	((family or families) near/2 (care or healthcare or intervention? or program* or service? or system?)):ti,ab

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

47	(transition* near/2 (plan? or planning or planned or coordinat* or co-ordinat* or care or healthcare or program* or intervention?)):ti,ab
48	{or 28-47}
49	18 and 27 and 48

MEDLINE Ovid, including Epub Ahead of Print, In-Process, & Other Non-Indexed Citations (1946 to present)

Search date: 5 May 2020, 20 January 2023

No.	**Search terms**
1	exp chronic disease/
2	((complex* or chronic* or rare or severe) adj2 (disease? or ill* or need? or problem? or condition?)).ti,ab,kf.
3	transition to adult care/
4	diabetes mellitus, type 1/
5	diabet*.ti,ab,kf.
6	exp asthma/
7	asthma*.ti,ab,kf.
8	exp cystic fibrosis/
9	cystic fibrosis.ti,ab,kf.
10	pediatric obesity/ or obesity/ or overweight/
11	(obese or obesit* or over weight or overweight).ti,ab,kf.
12	cerebral palsy.ti,ab,kf.
13	cerebral palsy/
14	anemia, sickle cell/
15	sickle cell.ti,ab,kf.
16	exp neoplasms/
17	(neoplasm? or cancer?).ti,ab,kf.
18	or/1-17
19	exp adolescent/
20	exp child/

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

21	exp infant/
22	child health services/
23	adolescent health services/
24	(adolescen* or babies or baby or boy? or boyhood or girlhood or child* or girl? or infan* or juvenil* or kid? or minors or minors* or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or puber* or pubescen* or school* or teen* or toddler? or underage? or under-age? or youth*).ti,ab,kf.
25	(pediatric* or paediatric* or infan* or child* or adolescen* or young).jn,jw.
26	(parent? or mother? or father? or family or families or carer?).ti,ab,kf.
27	or/19-26
28	case managers/
29	case management/
30	patient navigation/
31	patient-centered care/
32	transitional care/
33	mentors/
34	community health workers/
35	patient advocacy/
36	((health* or patient*) adj advoca*).ti,ab,kf.
37	community health worker?.ti,ab,kf
38	(case manager? or care manager?).ti,ab,kf.
39	((patient or care or healthcare or service? or communit* or system? or personal) adj3 navigat*).ti,ab,kf.
40	((care or healthcare or management) adj2 (coordinat* or co-ordinat*)).ti,ab,kf.
41	(team* adj2 (care or healthcare or treat* or assess* or consult* or program* or intervention?)).ti,ab,kf.
42	((integrat* or coordinat* or co-ordinat* or collaborat* or cooperat* or co-operat*) adj2 (care or healthcare or intervention? or program* or service? or system?)).ti,ab,kf.
43	(communit* and navigat*).ti,ab,kf.
44	((care or healthcare) adj2 ambassador?).ti,ab,kf.
45	((parent? or healthcare or care or mother? or father?) adj3 mentor?).ti,ab,kf.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

46	((family or families) adj2 (care or healthcare or intervention? or program* or service? or system?)).ti,ab,kf.
47	(transition* adj2 (plan? or planning or planned or coordinat* or co-ordinat* or care or healthcare or program* or intervention?)).ti,ab,kf.
48	or/28-47
49	exp randomized controlled trial/
50	controlled clinical trial.pt.
51	randomi#ed.ti,ab.
52	placebo.ab.
53	randomly.ti,ab.
54	clinical trials as topic.sh.
55	trial.ti.
56	or/49-51
57	exp animals/ not humans/
58	56 not 57
59	18 and 27 and 48 and 58

Embase Ovid (1974 to 31 July 2021); Embase Elsevier (1 January 2021 to 20 January 2023)

Search date: 5 May 2020, 20 January 2023

No.	Search terms
1	exp chronic disease/
2	((complex* or chronic* or rare or severe) adj2 (disease? or ill* or need? or problem? or condition?)).ti,ab,kw.
3	transition to adult care/
4	insulin dependent diabetes mellitus/
5	diabet*.ti,ab,kw.
6	exp asthma/
7	asthma*.ti,ab,kw.
8	cystic fibrosis/

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

9	cystic fibrosis.ti,ab,kw.
10	obesity/ or childhood obesity/
11	(obese or obesit* or over weight or overweight).ti,ab,kw.
12	cerebral palsy/
13	cerebral palsy.ti,ab,kw.
14	exp sickle cell anemia/
15	sickle cell.ti,ab,kw.
16	exp neoplasm/
17	(neoplasm? or cancer?).ti,ab,kw.
18	or/1-17
19	exp adolescent/
20	exp child/
21	exp infant/
22	exp child health care/
23	(adolescen* or babies or baby or boy? or boyhood or girlhood or child* or girl? or infan* or juvenil* or kid? or minors or minors* or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or puber* or pubescen* or school* or teen* or toddler? or underage? or under-age? or youth*).ti,ab,kw.
24	(pediatric* or paediatric* or infan* or child* or adolescen* or young).jn,jx.
25	(parent? or mother? or father? or family or families or carer?).ti,ab,kw.
26	or/19-25
27	case manager/
28	case management/
29	transitional care/
30	mentor/
31	health auxiliary/
32	patient advocacy/
33	((health* or patient*) adj advoca*).ti,ab,kw.
34	community health worker?.ti,ab,kw.
35	(case manager? or care manager?).ti,ab,kw.

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

36	((patient or care or healthcare or service? or communit* or system? or personal) adj3 navigat*).ti,ab,kw.
37	((care or healthcare or management) adj2 (coordinat* or co-ordinat*)).ti,ab,kw.
38	(team* adj2 (care or healthcare or treat* or assess* or consult* or program* or intervention?)).ti,ab,kw.
39	((integrat* or coordinat* or co-ordinat* or collaborat* or cooperat* or co-operat*) adj2 (care or healthcare or intervention? or program* or service? or system?)).ti,ab,kw.
40	(communit* and navigat*).ti,ab,kw.
41	((care or healthcare) adj2 ambassador?).ti,ab,kw.
42	((parent? or healthcare or care or mother? or father?) adj3 mentor?).ti,ab,kw.
43	((family or families) adj2 (care or healthcare or intervention? or program* or service? or system?)).ti,ab,kw.
44	(transition* adj2 (plan? or planning or planned or coordinat* or co-ordinat* or care or healthcare or program* or intervention?)).ti,ab,kw.
45	or/27-44
46	random*.ti,ab.
47	factorial*.ti,ab.
48	(crossover* or cross over*).ti,ab.
49	((doubl* or singl*) adj blind*).ti,ab.
50	(assign* or allocat* or volunteer* or placebo*).ti,ab.
51	crossover procedure/
52	single blind procedure/
53	randomized controlled trial/
54	double blind procedure/
55	or/46-54
56	exp animal/ not human/
57	55 not 56
58	18 and 26 and 45 and 57
59	limit 58 to embase

CINAHL (EBSCO)

Search date: 5 May 2020, 20 January 2023

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

No.	Search terms
S1	(MH "Chronic Disease+")
S2	TI (((complex* or chronic* or rare or severe) N2 (disease? or ill* or need? or problem? or condition?))) OR AB (((complex* or chronic* or rare or severe) N2 (disease? or ill* or need? or problem? or condition?)))
S3	(MH "Transitional Care")
S4	(MH "Diabetes Mellitus, Type 1")
S5	TI diabet* OR AB diabet*
S6	(MH "Asthma+")
S7	TI asthma* OR AB asthma*
S8	(MH "Cystic Fibrosis")
S9	TI cystic fibrosis OR AB cystic fibrosis
S10	(MH "Obesity") OR (MH "Pediatric Obesity")
S11	TI (obese or obesit* or over weight or overweight) OR AB (obese or obesit* or over weight or overweight)
S12	(MH "Cerebral Palsy")
S13	TI cerebral palsy OR AB cerebral palsy
S14	(MH "Anemia, Sickle Cell")
S15	TI sickle cell OR AB sickle cell
S16	(MH "Neoplasms+")
S17	TI (neoplasm? or cancer?) OR AB (neoplasm? or cancer?)
S18	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17
S19	(MH "Adolescence+") OR (MH "Child+") OR (MH "Minors (Legal)")
S20	(MH "Adolescent Health Services") OR (MH "Child Health Services")
S21	TI ((adolescen* or babies or baby or boy? or boyhood or girlhood or child* or girl? or infan* or juvenil* or kid? or minors or minors* or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or puber* or pubescen* or school* or teen* or toddler? or underage? or under-age? or youth*)) OR AB ((adolescen* or babies or baby or boy? or boyhood or girlhood or child* or girl? or infan* or juvenil* or kid? or minors or minors* or neonat* or neo-nat* or newborn* or new-born* or paediatric* or peadiatric* or pediatric* or perinat* or preschool* or puber* or pubescen* or school* or teen* or toddler? or underage? or under-age? or youth*))

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

S22	TI (parent? or mother? or father? or family or families or carer?) OR AB (parent? or mother? or father? or family or families or carer?)
S23	SO (pediatric* or paediatric* or infan* or child* or adolescen* or young)
S24	S19 OR S20 OR S21 OR S22 OR S23
S25	(MH "Case Managers") OR (MH "Case Management")
S26	(MH "Patient Navigation")
S27	(MH "Patient Centered Care")
S28	(MH "Transitional Care")
S29	(MH "Mentorship")
S30	(MH "Community Health Workers")
S31	(MH "Patient Advocacy")
S32	TI ((health* or patient*) N0 advoca*) OR AB ((health* or patient*) N0 advoca*)
S33	TI community health worker? OR AB community health worker?
S34	TI (case manager? or care manager?) OR AB (case manager? or care manager?)
S35	TI ((patient or care or healthcare or service? or communit* or system? or personal) N3 navigat*) OR AB ((patient or care or healthcare or service? or communit* or system? or personal) N3 navigat*)
S36	TI ((care or healthcare or management) N2 (coordinat* or co-ordinat*)) OR AB ((care or healthcare or management) N2 (coordinat* or co-ordinat*))
S37	TI (team* N2 (care or healthcare or treat* or assess* or consult* or program* or intervention?)) OR AB (team* N2 (care or healthcare or treat* or assess* or consult* or program* or intervention?))
S38	TI ((integrat* or coordinat* or co-ordinat* or collaborat* or cooperat* or co-operat*) N2 (care or healthcare or intervention? or program* or service? or system?)) OR AB ((integrat* or coordinat* or co-ordinat* or collaborat* or cooperat* or co-operat*) N2 (care or healthcare or intervention? or program* or service? or system?))
S39	TI (communit* and navigat*) OR AB (communit* and navigat*)
S40	TI ((care or healthcare) N2 ambassador?) OR AB ((care or healthcare) N2 ambassador?)
S41	TI ((parent? or healthcare or care or mother? or father?) N3 mentor?) OR AB ((parent? or healthcare or care or mother? or father?) N3 mentor?)
S42	TI ((family or families) N2 (care or healthcare or intervention? or program* or service? or system?)) OR AB ((family or families) N2 (care or healthcare or intervention? or program* or service? or system?))
S43	TI (transition* N2 (plan? or planning or planned or coordinat* or co-ordinat* or care or healthcare or program* or intervention?)) OR AB (transition* N2 (plan? or planning or planned or coordinat* or co-ordinat* or care or healthcare or program* or intervention?))

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

(Continued)

S44	S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43
S45	S18 AND S24 AND S44
S46	(MH "Random Assignment")
S47	(MH "Clinical Trials+")
S48	TI (randomis* or randomiz* or randomly) OR AB (randomis* or randomiz* or randomly)
S49	PT clinical trial
S50	PT randomized controlled trial
S51	S46 OR S47 OR S48 OR S49 OR S50
S52	S45 AND S51
S53	S52 Limiters - Exclude MEDLINE records

ClinicalTrials.gov

Search date: 5 May 2020

Field	Search terms
Condition/disease	chronic* OR complex* OR diabet* OR asthma* OR cystic fibrosis OR obese OR obesit* OR over weight OR overweight OR cerebral palsy OR sickle cell OR neoplasm* or cancer*
Intervention	navigat* OR case manag* OR care manag* OR mentor* OR advocate* OR community health worker*

World Health Organization International Clinical Trials Registry Platform (ICTRP)

Search date: 5 May 2020

No.	Search terms
	(pediatric* OR paediatric* OR infan* OR child* OR adolescen*) AND (navigat* OR case manag* OR care manag* OR mentor* OR advocate* OR community health worker*) AND (chronic* OR complex*)

Epistemonikos

Search date: 5 May 2020

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

	Search terms (Title/Abstract)
	pediatric* OR paediatric* OR infan* OR child* OR adolescen*
AND	navigat* OR case manag* OR care manag* OR mentor* OR advocate* OR community health worker*
AND	chronic* OR complex* OR diabet* OR asthma* OR cystic fibrosis OR obese OR obesit* OR over weight OR overweight OR cerebral palsy OR sickle cell OR neoplasm* or cancer*
	Limit to systematic review (PUBLICATION TYPE)

HISTORY

Protocol first published: Issue 7, 2021

CONTRIBUTIONS OF AUTHORS

Study selection: RL, LK, RK, CG

Extra data from studies: RL, LK

Enter data into Review Manager: RL, LK

Carry out analysis: RL, LK, GW

Interpret analysis: RL, AF, GW, DJ

Draft the final review: RL, LK, AF, GW, DJ

Disagreement resolution: RK, CG

DECLARATIONS OF INTEREST

RL: associate investigator for NAVKIDS2.

LK: none.

AF: investigator for NAVKIDS2.

RK: investigator for NAVKIDS2.

CG: investigator for NAVKIDS2.

DJ: Cochrane Editor. David, however, was not involved in the editorial process for this systematic review. DJ has received consultancy fees, research grants, speaker's honoraria and travel sponsorships from Baxter Healthcare and Fresenius Medical Care; consultancy fees from AstraZeneca, Bayer and AWAK; speaker's honoraria from Ono, Boehringer Ingelheim, and Lilly; and travel sponsorships from Ono and Amgen. He is a current recipient of an Australian National Health and Medical Research Council Leadership Investigator Grant.

GW: lead investigator for NAVKIDS2.

SOURCES OF SUPPORT

Internal sources

- Centre for Kidney Research, Australia

  Infrastructure and practical support
- Metro South Integrative Nephrology and Transplant Services (MINTS), Princess Alexandra Hospital Brisbane, Australia

  Infrastructure support

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

External sources

- Monash University, Monash Department of Clinical Epidemiology – Cabrini, Australia

  Infrastructure support
- Beat-CKD, Australia

  Research scholarship 2019 for RL
- Royal Australasian College of Physicians, Australia

  Jacquot Scholarship 2020 and 2021 for RL
- Australian National Health and Medical Research Council (NHMRC), Australia

  DJ and GW both currently receive research grants from NHMRC
- Industry funding, Australia

  DJ has received funding from Astra-Zeneca, Ono, AWAK, Baxter, and Amgen
- Royal Australasian College of Physicians, Australia

  Research grant 2021 for AF

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We made the following changes from the published protocol (Lalji 2021).

- Given the heterogeneity and small numbers of participants in these studies, we were unable to undertake any of the subgroup analyses as described a priori in the protocol.
- LK is the second author for the full review paper.
- We used Embase Elsevier in the most recent search update.

INDEX TERMS

Medical Subject Headings (MeSH)

*Chronic Disease [therapy]; *Patient Navigation

MeSH check words

Adolescent; Child; Humans

Copyright © 2024 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.