SYSTEMATIC REVIEW

Open Access



The use of implementation science theoretical approaches in hybrid effectiveness-implementation type 1 randomised trials of healthcare interventions: A scoping review

Orly Atzmon¹, Meagan E. Crowther¹, Bei Bei¹ and Denise A. O'Connor^{2*}

Abstract

Background Hybrid type 1 effectiveness-implementation randomised controlled trials (RCTs) aim to accelerate the translation of proven clinical interventions into routine care by concurrently investigating the effectiveness of clinical interventions and the context for real-world implementation. Hybrid type 1 RCTs can make use of implementation science theoretical approaches (i.e., theories, models, and frameworks) to understand barriers and facilitators to sustainable implementation of clinical interventions; however, the extent to which these approaches have been used in hybrid type 1 RCTs has not been systematically investigated. This scoping review aimed to investigate the extent to which implementation science theoretical approaches have been used in hybrid type 1 RCTs of health-care interventions and describe which approaches have been reported and how they have been used.

Methods The review was conducted in accordance with the pre-registered protocol (https://doi.org/10.17605/OSF. IO/CJ8A7). Searches of six electronic databases were conducted for published hybrid type 1 RCTs evaluating any clinical intervention in any healthcare setting. The included trials were full-text, peer-reviewed primary research articles written in English, and reporting the findings of hybrid type 1 RCTs of healthcare interventions. Non-English language reports, reviews, protocols without a linked trial results report, methodological papers, opinion pieces, commentaries, books/book chapters, dissertations, and conference abstracts were excluded. Two reviewers independently selected studies, extracted data, and assessed use of theoretical approach/es.

Results We identified 8,878 citations, screened 673 full-text records, and included 37 trials.

Most trials were conducted in North America (68%), investigating clinical interventions for mental health problems (32%) in adults (43%). Twenty-eight (76%) trials cited use of at least one theoretical approach. The most common was the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework (43%). Theoretical approaches were most often applied (62%) to justify the implementation study design, guide selection of study materials or analyse implementation outcomes.

*Correspondence: Denise A. O'Connor denise.oconnor@monash.edu Full list of author information is available at the end of the article



© The Author(s) 2025. **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by/4.0/.

Conclusion The majority of published hybrid type 1 effectiveness-implementation RCTs of healthcare interventions report using at least one theoretical approach to explore the context for implementation. Use of implementation science theories, models, and/or frameworks to understand the barriers and facilitators to implementation and sustainability of proven clinical interventions is likely to accelerate future translation of evidence-based practices into routine care and thus optimise patient outcomes.

Keywords Hybrid type 1 trial, Hybrid type 1 effectiveness-implementation randomised controlled trial, Implementation science, Theory, Model, Framework

Contributions to the literature

- This scoping review investigates and synthesises evidence on the usage of implementation science theories, models, and frameworks in hybrid type 1 effectivenessimplementation randomised controlled trials of healthcare interventions.
- By investigating to what extent and how these theories, models, and frameworks are used, this review offers valuable insights for future researchers in selecting appropriate theoretical approaches to explore the context for sustainable implementation of proven clinical interventions into routine care.
- Theory-informed assessments of barriers and facilitators to uptake of evidence-based clinical interventions informs the design of tailored implementation strategies, which may accelerate translation into routine practice.

Background

The traditional research trajectory to support translation of evidence-based clinical interventions into routine practice for improved patient care has emphasised a staged approach. This staged approach creates a time lag as it focusses on first establishing that a clinical intervention works under ideal conditions (i.e., performs well in efficacy and subsequent effectiveness trials and systematic reviews) before considering translation into routine practice [1]. More recently, this approach also includes de-implementation of clinical interventions that are demonstrated to be of little or no benefit, or are harmful to patients [2]. As a result, there is often a substantial time lag between the creation of an evidence-based clinical intervention and its widespread implementation within the community [3]. Hybrid effectiveness-implementation randomised controlled trials (RCTs) have been conceptualised to reduce this time lag and accelerate implementation of evidence-based clinical interventions into routine practice. Hybrid trial designs take a dual focus in assessing the effectiveness of a clinical intervention and its concurrent implementation [1]. Type 1 hybrid trials aim to concurrently investigate the effects of clinical interventions as well as the context for implementation. Type 2 hybrid trials assess the effects of clinical interventions while also exploring the feasibility and potential utility of implementation strategies to support their uptake. Type 3 hybrid trials assess the effects of implementation strategies on implementation as well as clinical outcomes [1].

There is value in using theories, models, and/or frameworks (TMFs) in implementation research [4]. TMFs can aide in exploring various factors influencing the implementation and sustainability of clinical interventions (e.g., barriers and facilitators), can inform the design of implementation strategies to support uptake of clinical interventions in routine health care, and facilitate evaluation of implementation outcomes [4, 5]. TMFs provide an understanding of the complex systems within which implementation occurs, and provide explicit assumptions that can be tested, validated, or refined in empirical studies [6]. TMFs also help to connect findings across studies from various clinical settings [7]. As such, they support efficiency in generalising knowledge across contexts, thereby advancing implementation science [6, 7]. Nilsen [4] has proposed a taxonomy of TMFs in implementation science (Table 1).

Numerous TMFs are available [4, 8, 9]. Yet, a comprehensive analysis of 235 implementation studies by Davies et al. [10] shows that less than one quarter use TMFs in any way, and only 6% are explicitly theory-based. More recent reviews by Colquhoun et al. [11] and McIntyre et al. [12] highlight a similar trend, where only 14% of randomised trials of audit and feedback interventions report use of TMFs, and only a quarter of process evaluations conducted alongside implementation trials are informed by, apply, or test TMFs, respectively. Therefore, the use of TMFs in implementation trials, and accompanying process evaluations, is suboptimal.

Hybrid type 1 effectiveness-implementation RCTs can utilise TMFs to better understand and describe the context for implementation of clinical interventions. By examining barriers and facilitators to implementation and sustainability, TMFs can provide valuable insights to understand how clinical interventions may function effectively in specific contexts, thereby informing the

Category	Description
Process models	They specify steps (stages, phases) in the process of translating research into practice, including the implementation and use of research
Determinant frameworks	They specify types of determinants and individual determinants, which act as barriers and enablers that influence imple- mentation outcomes
Classic theories	Theories that originate from fields external to implementation science, which can be applied to provide understanding and/ or explanation of aspects of implementation
Implementation theories	Theories that have been developed by implementation researchers to provide understanding and/or explanation of aspects of implementation
Evaluation frameworks	They specify aspects of implementation that could be evaluated to determine implementation success
Table adapted from Nilsen [4	4]

Table 1 Five categories of theories, models and frameworks used in implementation science

development of tailored strategies for successful integration of the interventions into routine practice [7]. To our knowledge, the extent to which TMFs are used in hybrid type 1 effectiveness-implementation RCTs of healthcare interventions has not been systematically investigated. To fill this gap, a scoping review was conducted to investigate the extent to which hybrid type 1 effectivenessimplementation RCTs report using one or more TMFs to explore the implementation context, and to describe which theoretical approaches have been reported and how they have been used. The objectives of this review are to: (1) investigate the proportion of hybrid type 1 effectiveness-implementation RCTs of healthcare interventions that explicitly report using one or more TMFs; (2) describe which TMFs are reported; and (3) examine how the TMFs are used.

Methodology

Study design

A scoping review method was selected as it is particularly useful for systematically mapping findings across a body of evidence that is diverse and complex [13]. The review was conducted in accordance with the Joanna Briggs Institute methodology for scoping reviews which is based on Arksey and O'Malley [14] and Levac et al. [15]. There are six steps including: (1) defining the research question/s, (2) identifying relevant studies, (3) study selection, (4) charting the data, (5) collating, summarising, and reporting the results, and (6) consultation. The present review is reported in line with Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping reviews (PRISMA-Scr) guidelines [16] (Additional File 1).

Protocol and registration

The scoping review protocol was pre-registered on January 19, 2024 (Open Science Framework: https://doi.org/ 10.17605/OSF.IO/CJ8A7). Prior to protocol registration, one author searched the Cochrane Database of Systematic Reviews, PROSPERO, and OSF, and determined that no similar reviews were already underway. The following sections describe the steps taken for conducting this scoping review. Quality appraisal was not undertaken as this review aimed to map whether and how TMFs are used in hybrid type 1 effectiveness-implementation RCTs rather than to synthesise the effects of clinical interventions, therefore, a quality assessment was not considered relevant.

Eligibility criteria

Types of studies

Studies were eligible for inclusion if they were hybrid type 1 effectiveness-implementation RCTs investigating the effectiveness of a healthcare clinical intervention while also exploring the context for implementation [1]. The included trials were full-text, peer-reviewed primary research articles written in English, and reporting the findings of a hybrid type 1 effectiveness-implementation RCTs. Non-English language reports, as well as reviews, protocols without a linked trial results report, methodological papers, opinion pieces, commentaries, books or book chapters, dissertations, and conference abstracts were excluded. Hybrid type 2 and 3 RCTs were not within the scope of the funded project and hence excluded. Date limits were set from when the effectiveness-implementation hybrid typology was published in March 2012 [1] as hybrid trials were not defined in research before this time. Multiple reports of the same trial found within our search, including publications such as protocols, reports of trial results, and qualitative or mixed-method reports, were collated so that each trial, rather than each report, was the unit of interest in the review.

Types of participants

The population of interest were participants who received the clinical interventions of interest in the hybrid type 1 effectiveness-implementation RCTs, healthcare providers who delivered the interventions, and/or stakeholders who were or would be interested in the interventions.

Types of interventions and settings

This review considered hybrid type 1 effectiveness-implementation RCTs that evaluated any clinical intervention in any healthcare setting. A healthcare intervention is defined as an intervention carried out to improve, maintain, or assess the health of a person in a clinical situation [17, 18]. An intervention that provided preventative intervention where a clinical condition was not present were excluded. Interventions that are not clinical interventions delivered in a healthcare setting were excluded. A healthcare setting includes hospitals (inpatient or outpatient care, acute or subacute phase), primary care, residential care, and the community. Excluded settings were where healthcare was not the primary function (e.g., correction facilities and services, community senior centres and schools).

Types of outcomes

Included trials explored the context for implementation and/or sustainability of the clinical intervention, including barriers and facilitators. Barriers refer to any factors reported to impede implementation efforts, and facilitators are any factors which enable implementation.

Search strategy

A two-step search was utilised in this review. The first step involved using search terms to retrieve hybrid type 1 effectiveness-implementation RCTs in six electronic databases (Ovid Medline, Ovid EMBASE, PsycINFO, CINAHL (EBSCO), Cochrane CENTRAL and Scopus). The second step involved citation tracking in Scopus of the original paper by Curran et al. [1] describing the effectiveness-implementation hybrid design typology (Additional File 2).

The search strategy in step one was developed in consultation with an academic librarian at Monash University. The search strategy was adapted for each chosen database, and Boolean operators and relevant controlled vocabulary terms were used as needed for each database search. RCT filters utilised in the search strategy were based on those reported in the Cochrane Handbook for Systematic Reviews of Interventions version 6.4 [19] for Medline (Ovid) and the Cochrane Embase RCT filters for Ovid, PsycINFO search strategy published by Eady et al. [20], and the Cochrane RCT filter for CINAHL Plus [21]. Initial database searches were conducted on 31st October 2023, with a final search performed on 26th November 2024 to identify any additional publications released between 31st October 2023 and 26th November 2024. All search results were managed in EndNote [22] and then exported to Covidence [23].

Selection of sources of evidence

Following deduplication, two reviewers (OA, MC) independently screened all titles and abstracts identified in the search according to the eligibility criteria. Following this, the same reviewers independently screened the full text of all potentially eligible records, recording reasons for exclusion of ineligible trials. Any disagreements in the screening and selection process were resolved through discussion between the two reviewers and, where needed, adjudication by a third reviewer (DO). Authors were contacted if clarification was needed for whether a publication was part of a trial. Additionally, reviewers carefully examined the aims and methods of trial reports to ensure that trials were hybrid type 1 effectiveness-implementation RCTs if they did not specify within publications. The search and screening results were summarised using a PRISMA flow chart.

Data charting process

Two reviewers (OA, MC) independently extracted data from the included trials using a standardised data extraction form developed by the research team (Additional File 3). Any disagreements were resolved through discussion between the reviewers and, where needed, adjudication by a third reviewer (DO). Prior to completing data extraction, the data extraction form was independently piloted by the two reviewers on 10 randomly selected publications. The pilot data extraction was then compared, discussed and the form refined to ensure consistency in content extracted.

Data items

Category 1: Trial characteristics

The following characteristics were extracted: publication title, year of publication, first author, source of publication (journal), country, trial aim/s, trial setting, type/s and number of participants in the effectiveness component of the trial, description of the clinical intervention, data collection and method/s for the implementation component of the trial, type/s and number of participants included in the implementation component of the trial.

Category 2: What TMFs were used

Data extracted included the name/s, source/s (if provided), type/s (Table 1) and number of TMFs cited. Reviewers categorised TMFs based on their alignment with Nilsen's [4] categories.

Category 3: How TMFs were used

The extent to which each TMF was used in the implementation component of the trial was categorised as one or more of the following: "informed by", "applied" or "cited only". Our scheme followed an adapted version of Painter et al. [24] classification, utilising the original "informed by" and "applied" categories, and excluding "testing theory" and "building or creating theory", as these are beyond the scope of hybrid type 1 effectivenessimplementation trials. Additionally, we added a "cited only" category to reflect trials that only cited a theory with no additional explanation or elaboration of how it was used [12]. "Applied" use was operationalised as the theoretical approach being specified with approximately half or more of the constructs applied in the implementation component of the trial (e.g., a trial described use of a theoretical approach to develop data collection tools (e.g., survey, interview topic guide) and the constructs were measured in the tools). "Informed by" was operationalised as the theoretical approach being specified with limited application within trial components and measures (e.g., a trial described use of a theoretical approach to inform qualitative data analysis but there was no evidence of the constructs being explored or examined). "Cited" was when a theoretical approach was mentioned or referenced in a trial without any further elaboration on how it was applied. Reviewers employed a descriptive approach to analyse qualitative data, further elaborating on the utilisation of TMFs. Such analysis aimed to ascertain the degree to which TMFs were applied or employed, facilitating a comprehensive evaluation of their usage. This analysis used themes adapted from McIntrye al's [12] categorisation for TMFs utilisation in process evaluations and Colquhoun et al. [11] category of justification of TMFs use for audit and feedback, both modified to fit the context of hybrid type 1 effectiveness-implementation trials. For trials that cited multiple TMFs, use was assessed for each individually.

Data synthesis

Extracted data were analysed to calculate the proportion of hybrid type 1 effectiveness-implementation RCTs utilising TMFs. Data analysis included frequency counts to identify the number of times each approach was used according to the use categories. The data synthesis was conducted by one reviewer (OA) and checked by a second reviewer (MC).

Results

Selection of sources of evidence

Database searches until the 26th of November 2024 retrieved a total of 8,878 records. After removing duplicates, 5,964 records remained for screening. Following title and abstract eligibility screening, 673 records remained for full-text review. Of these, 613 records were excluded for various reasons, including being protocols (n = 74; 12%), not being hybrid type 1 effectiveness-implementation designs (n = 280; 46%), and not being a RCT (n = 97; 16%). Clarification of the eligibility of 23 records was provided by a third reviewer (DO; Additional File 4). A total of 60 publications were eligible for inclusion in the review (Fig. 1), which represented 37 unique hybrid type 1 effectiveness-implementation RCTs.

Characteristics of included trials

A summary of the trial characteristics is provided in Additional file 5. Geographically, the studies were predominantly conducted in North America (68%), then Africa (14%), Europe (11%), Australia and New Zealand (5%), and Central and South America (3%). Intervention settings were primarily community-based (46%), with a smaller number conducted in primary care (24%), Veterans' affairs settings (19%), hospitals (5%), and nursing homes (5%). The target populations varied, with 43% of trials focussing on adults, 11% on women only, 11% on veterans, 8% on children, 8% on older adults and 3% on men only. A notable portion of included trials did not describe characteristics of the trial participants (16%). The majority (32%) of trials assessed the effects of clinical interventions for mental health problems, substance use problems (16%) and diabetes (14%).

Implementation characteristics

Most trials assessed implementation outcomes using a combination of interviews and questionnaires/checklists (n = 10; 27%), or interviews alone (n = 9; 24%). Questionnaires or checklists alone were used in four trials (11%), and chart reviews or report reviews were used in three trials (8%); Additional file 5). Participants in the implementation aspect of the trials comprised of intervention providers (n = 10; 29%), those who received the intervention in the effectiveness aspect of the trial (n = 6; 17%), relevant stakeholders (n = 4; 11%), and various combinations of these groups (43%); Additional File 5).

Synthesis of results

What proportion of trials cited TMFs and how were they used?

Of the 37 [25-83] included trials, 28 [25-70] (76%) used at least one TMF related to implementation, with 9 of these trials [25-34, 69] using two theoretical approaches,



Fig. 1 The PRISMA flowchart

Table 2 Extent to which theories, models and frameworks were used in included trials

	Frequency (%)	Trial citations
TMFs used	41	
Applied	32 (78.0)	[25–35, 37, 39–47, 49–53, 60, 69]
Informed by	7 (17.1)	[26, 33, 48, 54, 55, 69, 70]
Cited	2 (4.9)	[27, 50]

Trials may appear in multiple categories if they employed more than one theoretical approach, with each theory, model, or framework assessed individually. Additionally, only the implementation studies of the trials are referenced

and two trials [35-40] utilising three. At least one TMF was applied in 23 (62%) of the 28 trials, informed seven (19%) trials and was cited in two (5%) trials. Nine trials (24.3%) did not use any theoretical approach [71–83]. Overall, a theoretical approach was used 41 times across the 28 trials (see Table 2).

An analysis of the qualitative descriptions provided by trialists on how, and the extent to which, TMFs were used in the trials was conducted and is presented in Table 3 and Additional File 6 respectively. Most commonly, theoretical approaches were 'applied' to justify

 Table 3
 How theories, models and frameworks were used in included trials

	N (%)
Applied ^a	32/41
To select study materials and analyse data	17(41.5
To select study materials/design data collection	8(19.5)
To analyse data	2 (4.9)
To justify the study design and select study materials	3(<i>7.3)</i>
To justify the study design, select study materials and analyse data	1(2.4)
To justify the study design	1(2.4)
Informed by ^a	7/41
To support the implementation-related aims/objectives	4 <i>(9.8)</i>
To describe/explain the results	1(2.4)
To support the implementation-related aims/objectives and describe/explain the results	1(2.4)
Informed intervention	1(2.4)

^a Related to implementation component of trial

the design, select study materials, or analyse data (n = 23; 62%). For example, Arrossi et al. [37] used the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework in all stages of the research process, including conceptualisation, data collection, and analysis whilst Woodard et al. [41] used RE-AIM to evaluate implementation outcomes across its dimensions, specifically reach, adoption and implementation (see Additional File 6).

Numerous TMFs were used to develop implementation study materials, including interview or focus group topics guides [25, 34–36, 42–47] and questionnaire items [48]. Many TMFs also guided other data collection methods (i.e., chart reviews, intervention cost tracking, surveys, rating scales) [28, 29, 39, 49–51]. Additionally, RE-AIM and the Consolidated Framework for Implementation Research (CFIR) were used most frequently to analyse qualitative and/or quantitative data [26, 33, 34, 40, 46, 52, 69].

Less than one quarter of trials were 'informed by' one or more theoretical approaches to support the aims of the implementation component of the trial or to explain the results (n = 8; 22%). For example, two trials reported their trial hypothesis was informed by the Exploration, Preparation, Implementation and Sustainment (EPIS) [70] model and the RE-AIM framework [53]. Other trials indicated that a theoretical approach informed the interpretation of the implementation components of the trial, with Frost et al. [54] using Social Practice Theory, Petersen et al. [55] using RE-AIM, and Teupen et al. [69] using Grant et al.'s [84] framework for process evaluations of cluster randomised trials. Additionally, Chlebowski et al. [27] employed the Framework for Reporting Adaptations and Modifications-Enhanced (FRAME) to interpret their trial results. Another study by Minian et al. [33] utilised the Interactive Systems Framework (ISF) to guide the delivery of the intervention. Lastly, two trials only cited a theoretical approach [27, 50].

Of the 11 trials that utilised more than one TMF, two trials utilised three TMFs and both trials applied all TMFs with one trial applying RE-AIM, COM-B, and Self-Determination Theory to select study materials and analyse data [35, 36] and the other trial applying RE-AIM for the selection of study materials, analysis of data, and justification of the study design, while Proctor's Taxonomy was used to select study materials and CFIR was used to select materials and analyse data [37-40] (see Additional File 6). For studies that utilised two TMFs (9 trials), three trials applied both TMFs for the same purpose, with one trial using two TMFs to select study materials and analyse data [25], while the other two trials applied two TMFs to select study materials [28, 34]. Other trials applied both theoretical approaches in different ways. For instance, Proctor's taxonomy of implementation outcomes was used to justify the study design and select study materials, while RE-AIM was applied to select study materials and analyse the data [29, 30]. Another trial applied RE-AIM for selecting the study design and materials, while iPARIHS was used to justify the study design and select materials [31, 32]. Interestingly, four trials [27, 33, 69] applied one theoretical approach while being informed by or citing another.

Which TMFs were reported?

The most commonly reported theoretical approach was the RE-AIM framework, appearing in 12 out of 28 (43%) trials (see Table 4). This was followed by the CFIR, which was used in nine (32%) trials, and Proctor's taxonomy of implementation outcomes, used in four (14%) trials. Overall, evaluation frameworks were the most frequently employed theoretical approaches.

Discussion

Summary of evidence

This scoping review identified 60 publications reporting 37 hybrid type 1 effectiveness-implementation trials of healthcare interventions and examined the use of implementation science theoretical approaches in these studies. Three quarters of trials used at least one theoretical approach. Of these, nearly two thirds of studies 'applied' and nearly one quarter were 'informed by' one or more TMFs. Eleven trials used more than one TMF. The RE-AIM and CFIR frameworks were the most frequently

Table 4 TMFs reported in included trials

TMF category	TMF name (citation)	N (%) used	Trial citations
Evaluation fram	eworks		
	Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) [85]	12 (42.9)	[26, 28, 30, 31, 33, 34, 37, 40, 41, 43, 45, 53, 55]
	Proctor's taxonomy of implementation outcomes[86]	4 (14.3)	[27, 29, 39, 50]
	Grant et al [84] framework for process evaluations of cluster randomised trials	1 (3.6)	[69]
	Practical Robust Implementation Sustainability Model (PRISM) [87]	1 (3.6)	[51]
Determinant fra	Imeworks		
	Consolidated Framework for Implementation Research (CFIR) [88]	9 (32.1)	[25, 26, 34, 40, 42, 46, 47, 52, 69]
	Integrated Promoting Action on Research Implementation in Health Services (iPARiHS) [89, 90]	3 (10.7)	[28, 32, 49]
	Exploration, Preparation, Implementation and Sustainment (EPIS) [91]	1 (3.6)	[70]
	Nonadaptation, Abandonment, and Challenges to the Scale-up, Spread and Sustain- ability of Health and Care Technologies (NASSS) framework [92]	1 (3.6)	[35]
	Practical Robust Implementation Sustainability Model (PRISM) [87]	1 (3.6)	[51]
	Socio-ecological model [93]	1 (3.6)	[44]
Classic theories			
	Theory of Diffusion of Innovations [94]	2 (7.1)	[25, 48]
	Self-determination theory [95]	1 (3.6)	[35]
	Social Practice Theory [96]	1 (3.6)	[54]
Process models			
	Exploration, Preparation, Implementation and Sustainment (EPIS) [91]	1 (3.6)	[70]
	Interactive Systems Framework (ISF) for dissemination and implementation [97]	1 (3.6)	[33]
Implementation	n theories		
	Capability, Opportunity, Motivation and Behaviour (COM-B) [98]	1 (3.6)	[35]
	Organisation Readiness for Change Theory[99]	1 (3.6)	[60]

Two theoretical approaches (EPIS and PRISM) are coded in two of Nilsen's categories. Additionally, one framework (FRAME) could not be coded according to Nilsen's taxonomy as it appears to provide a checklist to assess adaptations and modifications to interventions.

used theoretical approaches. Evaluation frameworks, such as RE-AIM, were the most commonly used category of theoretical approach.

The finding that the majority of included trials utilised at least one theoretical approach is in contrast to McIntyre et al.'s [12] review in 2020 that found only 26% of studies utilised a TMF in process evaluations conducted alongside implementation trials. This suggests that the use of TMFs in trials may be increasing. This finding is a positive development, as the use of TMFs in hybrid effectiveness-implementation trials is likely to enhance the understanding of factors that may be important determinants of, and inform design of tailored implementation strategies to support, practice change if the clinical intervention is shown to be effective in the effectiveness component of the hybrid trial. The current review focussed on hybrid type 1 trials published since 2012, when Curran et al. [1] coined the term 'hybrid trials', whereas McIntyre et al. [12] focussed on process evaluations conducted alongside published implementation trials, and thus did not have a date limit. The inclusion of more recent trials in our review may be one possible explanation for the higher use of TMFs. This trend may also be influenced by recent efforts to categorise TMFs [4] and provide pragmatic guides for researchers on how to utilise TMFs in implementation projects [100, 101]. An additional potential explanation for the increased use of TMFs may be the recent emphasis on incorporating TMFs in grant proposals for implementation research [102, 103].

Our review highlighted that hybrid type 1 RCTs can utilise implementation science frameworks in numerous ways to provide actionable insights to inform future implementation efforts, for example, by informing selection or design of data collection tools, evaluating implementation outcomes, and analysing qualitative and/or quantitative data. Evaluation frameworks specify aspects of implementation that could be evaluated to determine implementation success [4]. Our finding that RE-AIM, an evaluation framework, was the most common theoretical approach used within the included trials is interesting considering hybrid type 1 trials aim to investigate the context for implementation, including barriers and facilitators to change, rather than evaluating current implementation success. Considering this focus of hybrid

type 1 trials, it is surprising that determinant frameworks (e.g., CFIR, PARiHS), which explicitly help in exploring the factors influencing implementation, were not more widely used. A possible explanation for this finding is that researchers conducting hybrid type 1 trials may not be as familiar with determinant frameworks and how they can help in exploring the factors influencing implementation of clinical interventions. Nonetheless, a scoping review of the usage of TMFs in implementation science found that determinant frameworks were the most commonly used [104], therefore the limited use of determinant frameworks could be due to other factors, which future research could explore. In addition to the CFIR, there are other determinant frameworks which were not reported in the included trials in our review but are likely to provide a useful basis for theorising the pathways to implementation of new evidence-based clinical practices (e.g., the Theoretical Domains Framework and the Model for Diffusion of innovations in Service Organisations) [101, 105-107].

Numerous implementation TMFs are available, making the selection process potentially challenging for researchers [108]. Recent advancements in the field, such as new guidance for researchers in selecting TMFs based on the 'goodness-of-fit' between the aims of the study and the characteristics of theoretical approaches, may be useful moving forward. For example, Lynch and colleagues [100] have proposed five questions to consider when selecting theoretical approach(es): (i) who are you working with? (e.g., individuals, groups or wider settings); (ii) when in the process are you going to use theory? (i.e., are you planning, conducting or evaluating?); (iii) why are you applying a theory? (i.e., what is your aim and what do you need to understand?); (iv) how will you collect data? (e.g., routinely collected data or data informed by the theoretical approach?); and (v) what resources are available? The implementation Theory Comparison and Selection Tool ('T-CaST') [109] is also available, informed by surveys and interviews with 37 implementation scientists across USA, the UK and Canada and containing 16 items across 4 domains (usability, testability, applicability, acceptability) to inform theory selection. Additionally, there are several resources that can support learning about implementation theoretical approaches. Websites for RE-AIM and CFIR, for example, help researchers keep upto-date with advances in these frameworks (e.g., https:// re-aim.org, https://cfirguide.org), whilst text books also summarise numerous implementation TMFs [110–112]. Furthermore, it may be useful for researchers with expertise in implementation science to be included in hybrid trial study teams from early in the research process to enhance the rigor and relevance of the implementation

aspects of these trials, ensuring that chosen TMFs are maximally useful and effectively applied.

Of the trials that utilised TMFs in our review, the majority 'applied' these approaches as opposed to the trials being 'informed by' them. Applying TMFs is considered a higher-level use than being informed by TMFs, with many trials applying them to guide data collection methods, develop interview guides and questionnaires, and analyse data. In contrast, trials that were 'informed by' one or more theoretical approaches used them primarily to support the aims of the implementation component of the trial, the interpretation of the implementation component, and for interpreting trial results. More trials 'applying' theoretical approaches suggests a deeper integration of implementation science principles into the design and execution of the implementation component of hybrid type 1 trials. Such integration of implementation science theoretical approaches provides a structured foundation for research, ensuring that studies are grounded in tested and validated concepts.

In the current review, many of the TMFs were challenging to categorise according to Nilsen's taxonomy [4] due to inadequate trial explanations and reporting. Future trials should provide more detailed descriptions of the theoretical approach/es used, including a clear explanation of how they were utilised in the context of the trial. Additionally, there was heterogeneity in reporting between the different publications of trials (e.g., mentioning a theoretical approach in the protocol paper but not specifying it in the paper reporting implementation aspects), which made identifying, categorising and synthesising the use of TMFs challenging. In our scoping review we categorised approaches according to Nilsen's [4] taxonomy of TMFs in implementation science to ensure consistency within the literature. This structured approach can contribute to more robust implementation science research, guiding researchers in selecting and applying the most appropriate TMFs in their trials.

The findings of the present review should be interpreted in light of key limitations. Firstly, of the 37 included trials, five were not explicitly labelled or described as hybrid type 1 effectiveness-implementation trial designs and were therefore classified as such based on whether they cited the original Curran et al. [1] publication and employed a methodology consistent with that of hybrid type 1 trials [28, 41, 50, 53, 74]. Therefore, it is possible that our search may have missed some hybrid type 1 trials that were not explicitly labelled as such. Our exclusion of non-English publications might bias the sample towards studies conducted in English-speaking countries. However, the exclusion of non-English publications has been shown not to significantly impact the direction or size of effect estimates [113]. Given most of the trials did not use Nilsen's [4] taxonomy and there was heterogeneity between reporting in publications, classifying theoretical approaches used in hybrid type 1 RCTs proved challenging.

Conclusions

This scoping review investigated the use of TMFs in hybrid type 1 effectiveness-implementation RCTs of healthcare interventions. It shows the majority of published hybrid type 1 RCTs report using at least one theoretical approach to explore the context for implementation of clinical interventions, with RE-AIM and CFIR being most common. Trials often lacked sufficient detail in reporting how TMFs were used. Future hybrid trials could address this gap by explicitly reporting whether and how TMFs are used.

Abbreviations

RCTs Randomised control trials TMFs Theories, Models, Frameworks

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s13012-025-01435-6.

(
Additional file 1.		
Additional file 2.		
Additional file 3.		
Additional file 4.		
Additional file 5.		
Additional file 6.		

Acknowledgements

This scoping review is being conducted as part of Orly Atzmon's PhD. Thanks to Mario Sos, liaison librarian at Monash University, for his guidance throughout the development of the search strategy.

Authors' contributions

OA and DO conceptualised the study and wrote the protocol. OA and DO wrote the background and methods for the study. OA and MC analysed the data and planned the output of the research. OA drafted the manuscript with input from DO, MC and BB. All authors approved the final manuscript.

Funding

No dedicated funding was received for this study. DO is supported by an Australian National Health and Medical Research Council (NHMRC) Investigator Fellowship (APP2025661).

Data availability

All data generated or analysed during this review will be included in the published article or be available by request from the study team.

Declarations

Ethics approval and consent to participate Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

¹School of Psychological Sciences, Monash University, Melbourne, Australia.
²School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia.

Received: 26 December 2024 Accepted: 2 May 2025 Published online: 16 May 2025

References

- Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012;50(3):217–26.
- 2. Norton W, Chambers D. Unpacking the complexities of de-implementing inappropriate health interventions. Implement Sci. 2020;15:2.
- Landes SJ, McBain SA, Curran GM. An introduction to effectivenessimplementation hybrid designs. Psychiatry Res. 2019;280: 112513.
- Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci. 2015;10(1):53.
- Moullin JC, Dickson KS, Stadnick NA, Albers B, Nilsen P, Broder-Fingert S, et al. Ten recommendations for using implementation frameworks in research and practice. Implementation Science Communications. 2020;1(1):42.
- Meza RD, Moreland JC, Pullmann MD, Klasnja P, Lewis CC, Weiner BJ. Theorizing is for everybody: Advancing the process of theorizing in implementation science. Front Health Serv. 2023;3:1134931.
- 7. Damschroder LJ. Clarity out of chaos: Use of theory in implementation research. Psychiatry Res. 2020;283: 112461.
- Strifler L, Cardoso R, McGowan J, Cogo E, Nincic V, Khan PA, et al. Scoping review identifies significant number of knowledge translation theories, models, and frameworks with limited use. J Clin Epidemiol. 2018;100:92–102.
- 9. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. Am J Prev Med. 2012;43(3):337–50.
- Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of guideline dissemination and implementation strategies and interpretation of the results of rigorous evaluations. Implement Sci. 2010;5(1):14.
- Colquhoun HL, Brehaut JC, Sales A, Ivers N, Grimshaw J, Michie S, et al. A systematic review of the use of theory in randomized controlled trials of audit and feedback. Implement Sci. 2013;8(1):66.
- McIntyre SA, Francis JJ, Gould NJ, Lorencatto F. The use of theory in process evaluations conducted alongside randomized trials of implementation interventions: A systematic review. Transl Behav Med. 2020;10(1):168–78.
- Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol. 2018;18(1):143.
- 14. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005;8(1):19–32.
- 15. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci. 2010;5(1):69.
- Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Ann Intern Med. 2018;169(7):467–73.
- Health Alo, Welfare. Australia's health 2016. Canberra: AIHW; 2016. Accessed October 2023.
- 18. Clarke GM, Conti S, Wolters AT, Steventon A. Evaluating the impact of healthcare interventions using routine data. BMJ. 2019;365: I2239.
- Higgins JPT TJ, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.4 (updated August 2023). Available from www.training.cochr ane.org/handbook.: Cochrane; 2023.

- 20. Eady AM, Wilczynski NL, Haynes RB. PsycINFO search strategies identified methodologically sound therapy studies and review articles for use by clinicians and researchers. J Clin Epidemiol. 2008;61(1):34–40.
- Glanville J FR, Wisniewski S, Noel-Storr A, Edwards M, Dooley G. Translating the Cochrane EMBASE RCT filter from the Ovid interface to Embase. com: a case study. Health Info Libr J. 2019;36(3):264–77.
- 22. Clarivate. Endnote 2014 21:Available from: https://endnote.com/. Accessed February 2024.
- 23. Covidence systematic review software. Available from: www.covidence. org. Accessed October 2023.
- 24. Painter JE, Borba CPC, Hynes M, Mays D, Glanz K. The Use of Theory in Health Behavior Research from 2000 to 2005: A Systematic Review. Ann Behav Med. 2008;35(3):358–62.
- Cabassa LJ, Stefancic A. Context before implementation: A qualitative study of decision makers' views of a peer-led healthy lifestyle intervention for people with serious mental illness in supportive housing. Transl Behav Med. 2019;9(2):217–26.
- Paulsen MM, Varsi C, Andersen LF. Process evaluation of the implementation of a decision support system to prevent and treat disease-related malnutrition in a hospital setting. BMC Health Serv Res. 2021;21(1):281.
- Chlebowski C, Hurwich-Reiss E, Wright B, Brookman-Frazee L. Using stakeholder perspectives to guide systematic adaptation of an autism mental health intervention for Latinx families: A qualitative study. J Community Psychol. 2020;48(4):1194–214.
- Hagedorn HJ, Stetler CB, Bangerter A, Noorbaloochi S, Stitzer ML, Kivlahan D. An implementation-focused process evaluation of an incentive intervention effectiveness trial in substance use disorders clinics at two Veterans Health Administration medical centers. Addict Sci Clin Pract. 2014;9(101316917):12.
- Magidson JF, Joska JA, Belus JM, Andersen LS, Regenauer KS, Rose AL, et al. Project Khanya: results from a pilot randomized type 1 hybrid effectiveness-implementation trial of a peer-delivered behavioural intervention for ART adherence and substance use in HIV care in South Africa. J Int AIDS Soc. 2021;24(S2): e25720.
- Magidson JF, Joska JA, Myers B, Belus JM, Regenauer KS, Andersen LS, et al. Project Khanya: a randomized, hybrid effectiveness-implementation trial of a peer-delivered behavioral intervention for ART adherence and substance use in Cape Town, South Africa. 2020;1.
- Almeida FA, Michaud TL, Wilson KE, Schwab RJ, Goessl C, Porter GC, et al. Preventing diabetes with digital health and coaching for translation and scalability (PREDICTS): A type 1 hybrid effectiveness-implementation trial protocol. Contemp Clin Trials. 2020;88: 105877.
- Michaud TL, Wilson K, Silva F, Almeida F, Katula J, Estabrooks P. Costing a population health management approach for participant recruitment to a diabetes prevention study. Translational behavioral medicine. 2021;11(10):1864–74.
- Minian N, Lingam M, Moineddin R, Thorpe KE, Veldhuizen S, Dragonetti R, et al. The Impact of a Clinical Decision Support System for Addressing Physical Activity and Healthy Eating During Smoking Cessation Treatment: Hybrid Type I Randomized Controlled Trial. J Med Internet Res. 2022;24(9): e37900.
- 34. Ventuneac A, Li DH, Mongrella MC, Moskowitz DA, Weingardt KR, Brown CH, et al. Exploring Potential Implementation Barriers and Facilitators of the SMART Program: A Stepped-Care Package of eHealth HIV Prevention Interventions for Adolescent Men Who Have Sex with Men. Sex Res Soc Policy. 2020;17(3):378–88.
- Dawson R, Gilchrist H, Pinheiro M, Nelson K, Bowes N, Sherrington C, et al. Experiences of Older Adults, Physiotherapists, and Aged Care Staff in the TOP UP Telephysiotherapy Program: interview Study of the TOP UP Interventions. JMIR aging. 2024;7: e53010.
- Dawson R, Pinheiro M, Nagathan V, Taylor M, Delbaere K, Olivera J, et al. Physiotherapy-led telehealth and exercise intervention to improve mobility in older people receiving aged care services (TOP UP): protocol for a randomised controlled type 1 hybrid effectiveness-implementation trial. BMJ nutrition, prevention & health. 2023;6(2):273–81.
- 37. Arrossi S, Paolino M, Antelo VS, Thouyaret L, Kohler RE, Cuberli M, et al. Effectiveness of an mHealth intervention to increase adherence to triage of HPV DNA positive women who have performed self-collection (the ATICA study): A hybrid type I cluster randomised effectivenessimplementation trial. 2022;9.

- 38. Arrossi S, Paolino M, Orellana L, Thouyaret L, Kohler RE, Viswanath K. Mixed-methods approach to evaluate an mHealth intervention to increase adherence to triage of human papillomavirus-positive women who have performed self-collection (the ATICA study): study protocol for a hybrid type I cluster randomized effectiveness-implementation trial. Trials. 2019;20(1):148.
- Paolino M, Sanchez Antelo V, Kohler RE, Viswanath K, Arrossi S. Implementation of an mHealth intervention to increase adherence to triage among HPV positive women with HPV-self-collection (ATICA study): post-implementation evaluation from the women's perspective. BMC Womens Health. 2023;23(1):332.
- 40. Straw C, Sanchez-Antelo V, Kohler R, Paolino M, Viswanath K, Arrossi S. Implementation and scaling-up of an effective mHealth intervention to increase adherence to triage of HPV-positive women (ATICA study): perceptions of health decision-makers and health-care providers. BMC Health Serv Res. 2023;23(1):47.
- Woodard L, Amspoker AB, Hundt NE, Gordon HS, Hertz B, Odom E, et al. Comparison of Collaborative Goal Setting with Enhanced Education for Managing Diabetes-Associated Distress and Hemoglobin A1cLevels: A Randomized Clinical Trial. JAMA Netw Open. 2022;5(5):1–13.
- Baloh J, Curran GM, Timko C, Grant KM, Cucciare MA. Al-Anon Intensive Referral (AIR): A qualitative formative evaluation for implementation. J Subst Abuse Treat. 2022;132:1–15.
- Boden MT, Gaudiano BA, Walser RD, Timko C, Faustman W, Yasmin S, et al. Feasibility and challenges of inpatient psychotherapy for psychosis: lessons learned from a veterans health administration pilot randomized controlled trial. BMC Res Notes. 2016;9(101462768):376.
- 44. Krauss V, Mertens A, Marchak JG, Haardorfer R, Meacham LR, Lewis RW, et al. Clinic reported facilitators and barriers to pediatric cancer survivor care delivery among survivorship clinics: A fishbone analysis. Pediatr Blood Cancer. 2023;70(8): e30480.
- 45. Lewis MA, Wagner LK, Rosas LG, Lv N, Venditti EM, Steinman LE, et al. Using RE-AIM to examine the potential public health impact of an integrated collaborative care intervention for weight and depression management in primary care: Results from the RAINBOW trial. PLoS ONE. 2021;16(3):1–19.
- Nelson LA, Roddy MK, Bergner EM, Gonzalez J, Gentry C, Lestourgeon LM, et al. Exploring determinants and strategies for implementing self-management support text messaging interventions in safety net clinics. J Clin Transl Sci. 2022;6(1):1–9.
- 47. Reckrey JM, Gazarian P, Reuben DB, Latham NK, McMahon SK, Siu AL, et al. Barriers to implementation of STRIDE, a national study to prevent fall-related injuries. J Am Geriatr Soc. 2021;69(5):1334–42.
- Elwy AR, Kim B, Plumb DN, Wang S, Gifford AL, Asch SM, et al. The Connectedness of Mental Health Providers Referring Patients to a Treatment Study for Post-Traumatic Stress: A Social Network Study. Adm Policy Ment Health. 2020;47(2):197–209.
- Purcell N, Becker WC, Zamora KA, McGrath SL, Hagedorn HJ, Fabian ER, et al. Tailored to Fit: How an Implementation Framework Can Support Pragmatic Pain Care Trial Adaptation for Diverse Veterans Affairs Clinical Settings. Med Care. 2020;58:S80–7.
- Vandermorris A, McKinnon B, Sall M, Witol A, Traore M, Lamesse-Diedhiou F, et al. Adolescents' experiences with group antenatal care: Insights from a mixed-methods study in Senegal. Tropical Med Int Health. 2021;26(12):1700–8.
- Smith LR, Perez-Brumer A, Nicholls M, Harris J, Allen Q, Padilla A, et al. A data-driven approach to implementing the HPTN 094 complex intervention INTEGRA in local communities. Implementation Science. 2024;19(1):1–14.
- Vest BM, Wray LO, Brady LA, Thase ME, Beehler GP, Chapman SR, et al. Primary care and mental health providers' perceptions of implementation of pharmacogenetics testing for depression prescribing. BMC Psychiatry. 2020;20(1):1–10.
- Vousden N, Lawley E, Seed PT, Gidiri MF, Charantimath U, Makonyola G, et al. Exploring the effect of implementation and context on a stepped-wedge randomised controlled trial of a vital sign triage device in routine maternity care in low-resource settings. Implement Sci. 2019;14(1):1–16.
- 54. Frost J, Wingham J, Britten N, Greaves C, Abraham C, Warren FC, et al. The value of social practice theory for implementation science:

learning from a theory-based mixed methods process evaluation of a randomised controlled trial. BMC Med Res Methodol. 2020;20(1):181.

- Petersen I, Selohilwe O, Georgeu-Pepper D, Ras CJ, Zani B, Petrus R, et al. A collaborative care package for depression comorbid with chronic physical conditions in South Africa. BMC Health Serv Res. 2022;22(1):1–14.
- Brookman-Frazee L, Roesch S, Chlebowski C, Baker-Ericzen M, Ganger W. Effectiveness of training therapists to deliver an individualized mental health intervention for children with asd in publicly funded mental health services: A cluster randomized clinical trial. JAMA Psychiat. 2019;76(6):574–83.
- 57. Granholm E, Holden JL, Sommerfeld D, Rufener C, Perivoliotis D, Mueser K, et al. Enhancing assertive community treatment with cognitive behavioral social skills training for schizophrenia: study protocol for a randomized controlled trial. Trials. 2015;16:438.
- Fairall L, Petersen I, Zani B, Folb N, Georgeu-Pepper D, Selohilwe O, et al. Collaborative care for the detection and management of depression among adults receiving antiretroviral therapy in South Africa: study protocol for the CobALT randomised controlled trial. Trials. 2018;19(1):193.
- Goldstein KM, Fisher DA, Wu RR, Orlando LA, Coffman CJ, Grubber JM, et al. An electronic family health history tool to identify and manage patients at increased risk for colorectal cancer: protocol for a randomized controlled trial. Trials. 2019;20(1):576.
- Voils CI, Coffman CJ, Wu RR, Grubber JM, Fisher DA, Strawbridge EM, et al. A Cluster Randomized Trial of a Family Health History Platform to Identify and Manage Patients at Increased Risk for Colorectal Cancer. J Gen Intern Med. 2023;38(6):1375–83.
- Ma Y, Gow BJ, Song R, Rist PM, Hausdorff JM, Lipsitz LA, et al. Long-term Tai Chi practice in older adults is associated with "younger" functional abilities. Aging Cell. 2024;23(1): e14023.
- 62. Venditti EM, Steinman LE, Lewis MA, Weiner BJ, Ma J. Seeking a pot of gold with integrated behavior therapy and research to improve health equity: insights from the RAINBOW trial for obesity and depression. Transl Behav Med. 2021;11(9):1691–8.
- Belus JM, Rose AL, Andersen LS, Ciya N, Joska JA, Myers B, et al. Adapting a Behavioral Intervention for Alcohol Use and HIV Medication Adherence for Lay Counselor Delivery in Cape Town, South Africa: A Case Series. Cogn Behav Pract. 2022;29(2):454–67.
- Cabassa LJ, Stefancic A, Lewis-Fernández R, Luchsinger J, Weinstein LC, Guo S, et al. Main Outcomes of a Peer-Led Healthy Lifestyle Intervention for People With Serious Mental Illness in Supportive Housing. Psychiatr Serv. 2021;72(5):555–62.
- Cabassa LJ, Stefancic A, O'Hara K, El-Bassel N, Lewis-Fernández R, Luchsinger JA, et al. Peer-led healthy lifestyle program in supportive housing: study protocol for a randomized controlled trial. Trials. 2015;16:388.
- 66. Tuda D, Bochicchio L, Stefancic A, Hawes M, Chen JH, Powell BJ, et al. Using the matrixed multiple case study methodology to understand site differences in the outcomes of a Hybrid Type 1 trial of a peer-led healthy lifestyle intervention for people with serious mental illness. Translational behavioral medicine. 2023((Tuda, Hawes, Chen, Powell, Cabassa) George Warren Brown School of Social Work, Washington University in St. Louis Campus Box 1196 ,One Brookings Drive, St. Louis, United States(Tuda, Hawes, Powell, Cabassa) Center for Mental Health Services Research, Bro).
- 67. Nelson LA, Wallston KA, Kripalani S, Greevy RA Jr, Elasy TA, Bergner EM, et al. Mobile Phone Support for Diabetes Self-Care Among Diverse Adults: Protocol for a Three-Arm Randomized Controlled Trial. JMIR Res Protoc. 2018;7(4): e92.
- Minian N, Lingam M, Moineddin R, Thorpe KE, Veldhuizen S, Dragonetti R, et al. Impact of a Web-Based Clinical Decision Support System to Assist Practitioners in Addressing Physical Activity and/or Healthy Eating for Smoking Cessation Treatment: Protocol for a Hybrid Type I Randomized Controlled Trial. JMIR Res Protoc. 2020;9(9): e19157.
- 69. Teupen S, Holle D, Roes M. Types of implementation of the dementiaspecific case conference concept WELCOME-IdA in nursing homes: a qualitative process evaluation of the FallDem effectiveness trial. Implement Sci Commun. 2021;2(1):1–12.
- 70. Sommerfeld DH, Granholm E, Holden J, Seijo C, Rapoport CS, Mueser KT, et al. Concept mapping study of stakeholder perceptions of

implementation of cognitive-behavioral social skills training on assertive community treatment teams. Psychol Serv. 2021;18(1):33–41.

- Binns E, Bright F, Parsons J, Peri K, Taylor L, Kerse N, et al. "It's all about the money": an interpretive description of embedding physical therapy-led falls prevention group exercise in long-term care. BMC Geriatr. 2023;23(1):1–10.
- Brady JE, Livingston NA, Sawdy M, Yeksigian K, Zhou S, Bickmore TW, et al. Development and Evaluation of a Relational Agent to Assist with Screening and Intervention for Unhealthy Drinking in Primary Care. J technol behav sci. 2023;4:432–45.
- Rubin A, Livingston NA, Brady J, Hocking E, Bickmore T, Sawdy M, et al. Computerized Relational Agent to Deliver Alcohol Brief Intervention and Referral to Treatment in Primary Care: a Randomized Clinical Trial. J Gen Intern Med. 2022;37(1):70–7.
- Ellis DA, Carcone AI, Naar-King S, Rajkumar D, Palmisano G, Moltz K. Adaptation of an Evidence-Based Diabetes Management Intervention for Delivery in Community Settings: Findings From a Pilot Randomized Effectiveness Trial. J Pediatr Psychol. 2019;44(1):110–25.
- Garner BR, Burrus O, Ortiz A, Tueller SJ, Peinado S, Hedrick H, et al. A Longitudinal Mixed-Methods Examination of Positive Health Check: Implementation Results From a Type 1 Effectiveness-Implementation Hybrid Trial. J Acquir Immune Defic Syndr (1999). 2022;91(1):47–57.
- Lewis MA, Harshbarger C, Bann C, Burrus O, Peinado S, Garner BR, et al. Positive Health Check evaluation: A type 1 hybrid design randomized trial to decrease HIV viral loads in patients seen in HIV primary care. Contemp Clin Trials. 2020;96: 106097.
- Lewis MA, Harshbarger C, Bann C, Marconi VC, Somboonwit C, Piazza MD, et al. Effectiveness of an Interactive, Highly Tailored "Video Doctor" Intervention to Suppress Viral Load and Retain Patients With HIV in Clinical Care: A Randomized Clinical Trial. J Acquir Immune Defic Syndr (1999). 2022;91(1):58–67.
- Meffert SM, Neylan TC, McCulloch CE, Blum K, Cohen CR, Bukusi EA, et al. Interpersonal psychotherapy delivered by nonspecialists for depression and posttraumatic stress disorder among Kenyan HIV– positive women affected by gender-based violence: Randomized controlled trial. PLoS Med. 2021;18(1):1–22.
- Onu C, Ongeri L, Bukusi E, Cohen CR, Neylan TC, Oyaro P, et al. Interpersonal psychotherapy for depression and posttraumatic stress disorder among HIV-positive women in Kisumu, Kenya: study protocol for a randomized controlled trial. Trials. 2016;17(1):64.
- Pelletier C, Chabot C, Gagnon MP, Rhéaume C. Implementing an Activity Tracker to Increase Motivation for Physical Activity in Patients With Diabetes in Primary Care: Strengths, Weaknesses, Opportunities and Threats (SWOT) Analysis. JMIR Form Res. 2023;7:1–14.
- Smith JD, Stormshak EA, Kavanagh K. Results of a pragmatic effectiveness-implementation hybrid trial of the Family Check-up in community mental health agencies. Adm Policy Ment Health. 2015;42(3):265–78.
- 82. Smit MMC, Waal E, Tenback DE, Deenik J. Evaluating the implementation of a multidisciplinary lifestyle intervention for people with severe mental illness in sheltered housing: effectiveness-implementation hybrid randomised controlled trial. BJPsych open. 2022;8(6): e201.
- Shepardson RL, Weisberg RB, Wade M, Maisto SA, Funderburk JS. Brief modular anxiety intervention for primary care: Hybrid I pilot randomized controlled trial of feasibility, acceptability, effectiveness, and implementation potential. J Affect Disord. 2024;361:497–507.
- Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. Trials. 2013;14(1):15.
- Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89(9):1322–7.
- Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65–76.
- Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. Jt Comm J Qual Patient Saf. 2008;34(4):228–43.
- 88. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into

practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4(1):50.

- Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. Implement Sci. 2016;11(1):33.
- Kitson A, Harvey G, McCormack B. Enabling the implementation of evidence based practice: a conceptual framework. Qual Health Care. 1998;7(3):149.
- Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. Adm Policy Ment Health. 2011;38(1):4–23.
- Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res. 2017;19(11): e367.
- 93. Glanz K, Rimer BK, Viswanath K. Health behavior: Theory, research, and practice. San Francisco: Wiley; 2015.
- 94. Rogers Everett M. Diffusion of innovations. New York: Free Press trade paperback edition; 1995.
- Ryan RM, Deci EL. Self-determination theory: Basic psychological needs in motivation, development, and wellness. New York, NY, US: The Guilford Press; 2017. p. 756-xii.
- 96. Shove E, Pantzar M, Watson M. The Dynamics of Social Practice: Everyday Life and How it Changes. London2012. Available from: https://sk. sagepub.com/books/the-dynamics-of-social-practice.
- Wandersman A, Duffy J, Flaspohler P, Noonan R, Lubell K, Stillman L, et al. Bridging the gap between prevention research and practice: the interactive systems framework for dissemination and implementation. Am J Community Psychol. 2008;41(3–4):171–81.
- Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42.
- 99. Weiner BJ. A theory of organizational readiness for change. Implement Sci. 2009;4(1):67.
- Lynch EA, Mudge A, Knowles S, Kitson AL, Hunter SC, Harvey G. "There is nothing so practical as a good theory": a pragmatic guide for selecting theoretical approaches for implementation projects. BMC Health Serv Res. 2018;18(1):857.
- Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci. 2017;12(1):77.
- Stadnick NA, Viglione C, Crable EL, Montoya JL, Gholami M, Su I, et al. Enhancing review criteria for dissemination and implementation science grants. Implementation Science Communications. 2023;4(1):17.
- Proctor EK, Powell BJ, Baumann AA, Hamilton AM, Santens RL. Writing implementation research grant proposals: ten key ingredients. Implement Sci. 2012;7(1):96.
- 104. Wang Y, Wong EL-Y, Nilsen P, Chung VC-h, Tian Y, Yeoh E-K. A scoping review of implementation science theories, models, and frameworks — an appraisal of purpose, characteristics, usability, applicability, and testability. Implement Sci. 2023;18(1):43.
- Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci. 2012;7:37.
- Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581–629.
- Francis JJ, O'Connor D, Curran J. Theories of behaviour change synthesised into a set of theoretical groupings: introducing a thematic series on the theoretical domains framework. Implement Sci. 2012;7(1):35.
- Strifler L, Barnsley JM, Hillmer M, Straus SE. Identifying and selecting implementation theories, models and frameworks: a qualitative study to inform the development of a decision support tool. BMC Med Inform Decis Mak. 2020;20(1):91.
- Birken SA, Rohweder CL, Powell BJ, Shea CM, Scott J, Leeman J, et al. T-CaST: an implementation theory comparison and selection tool. Implement Sci. 2018;13(1):143.
- Nilsen P, Birken SA, Nilsen P. Overview of theories, models and frameworks in implementation science. United Kingdom: Edward Elgar Publishing; 2020. p. 8–31.

- 111. Nilsen P. Implementation science : theory and application. First edition. ed. Abingdon, England: Routledge; 2024.
- 112. Michie S, West R, Campbell R, Brown J, Gainforth H. ABC of Behaviour Change Theories. London: Silverback publishing; 2014.
- 113. Nussbaumer-Streit B, Klerings I, Dobrescu AI, Persad E, Stevens A, Garritty C, et al. Excluding non-English publications from evidencesyntheses did not change conclusions: a meta-epidemiological study. J Clin Epidemiol. 2020;118:42–54.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.