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ORIGINAL RESEARCH

Recording harms in randomized controlled trials of behavior change interventions: a scoping review and map of the evidence

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Abstract

Objectives: Randomized controlled trials evaluate diverse interventions. This can include medical interventions such as drugs or surgical procedures, or behavior change interventions (BCIs) that aim to change a habit, belief, or attitude to improve health, for example, healthy eating, psychological wellbeing. Harms are often recorded poorly or inconsistently within randomized controlled trials of BCIs. This scoping review aimed to collate and describe literature on categories, definitions, and mechanisms of harms from BCIs; methods of identifying plausible harms; and recommendations for recording harms.

Study Design and Setting: A scoping review was conducted. Three databases (MEDLINE, PsycINFO, and CINAHL) were searched. Reference list checking and citation searching were performed. Articles were included if they discussed (1) interventions that aimed to modify behavior, (2) categories or mechanisms of harms, and (3) methods or recommendations for recording harms. All research designs were included. One reviewer reviewed titles, abstracts, and full texts; queries were checked with another reviewer. Data were extracted and synthesized descriptively by one reviewer and checked by another reviewer. A thematic map was constructed to summarize the review findings. Harms described from specific BCIs were identified, and examples were selected and summarized.

Results: The review included 37 articles. Nineteen of 37 articles contributed to a thematic review. Three articles described categories of harms; categories of harm included physical, psychological, group and social interactions, cultural, equity, opportunity cost, environmental, and economic. Seven articles included mechanisms or underlying factors for harms including feelings of failure leading to shame or stigma, and group interventions enabling knowledge exchange on unhealthy behaviors. Twelve articles provided recommendations for recording harms, including taking a proportionate approach by focusing on the most plausible and important harms, collecting different perspectives on whether harms had occurred (eg, caregivers and family members), and using qualitative research methods to identify harms. One article described a three-step method to identify plausible harms from an intervention, and six articles supported aspects of the method. Eighteen of 37 articles contributed to a review which collated harms arising from specific interventions, for example, a peer support intervention in inflammatory bowel disease caused distressing conversations which might lead to anxiety and confrontation with a possible negative future.

Conclusion: BCIs can cause harm. This review identified categories and proposed mechanisms of harms, as well as methods and recommendations for identifying and recording harms in BCIs for inclusion in forthcoming recommendations.

Keywords: Adverse events; Harms categories; Harms mechanisms; Behavior change; Randomized controlled trials; Scoping review

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Plain language summary

Background: Randomized controlled trials are used to assess various interventions, like medical treatments (such as drugs or surgeries) or efforts to change behavior such as improving mental wellbeing or healthy habits. Trials which assess behavior change interventions often collect negative effects known as ''harms'' poorly.

We looked at the literature to find types of harms that might occur in behavior change interventions. We looked at the ways harms might occur, known as ''mechanisms''. We also explored methods and recommendations for recording harms for behavior change intervention trials.

We found 37 articles. Of these, 19 contributed to a thematic review. Three articles categorized harms as physical, psychological, group and social interactions, cultural, equity, opportunity cost, environmental, and economic. Seven articles described mechanisms or factors underlying harms, such as feelings of failure leading to shame or stigma. Twelve provided recommendations for recording harms such as proportionate approach, considering perspectives on harms (eg, caregivers and family members), and using qualitative research methods. One article presented a three-step method for identifying plausible harms, with six articles supporting this method. Eighteen articles demonstrated harms arising from specific interventions, like a peer support initiative causing distressing conversations in inflammatory bowel disease.

Conclusion: Behavior change interventions can lead to harm. This review identified harm categories, proposed mechanisms, and suggested methods and recommendations for identifying and recording harms in behavior change interventions. The findings from this review will contribute to future recommendations on the subject.

1. Introduction

Randomized controlled trials (RCTs) evaluate diverse types of interventions, assessing both their benefits and harms. Medical interventions include drugs, devices, or procedures such as surgery. Behavior change interventions (BCIs) modify habits, for example, physical activity or diet, or beliefs and attitudes that affect psychological wellbeing, for example, cognitive behavioral therapy [1].

Harms are inconsistently and poorly recorded in RCTs of BCIs [2−6] This may be due to a misconception that these interventions cannot cause harm. However, empirical examples demonstrate harms can arise from BCIs [4,7−10] and the Consolidated Standards of Reporting Trials (CONSORT) Social and Psychological Interventions extension notes the potential for unintended harmful effects [11].

The CONSORT Harms extension provides detailed recommendations on how to report harms in RCTs and recommends defining harm as ''*the totality of possible adverse consequences of an intervention or therapy; they are the direct opposite of benefits, against which they must be compared*'' [12]. However, a systematic review of 151 BCI trial protocols found that 52% provided no definition for nonserious harms, while 25% defined them as ''*Adverse events: an untoward medical occurrence*.'' in line with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) definition for harms originally designed for pharmaceutical trials[1] [13].

Defining harms as ''adverse events'' may mean that harms from BCIs are not captured. For example, targeted social and emotional learning interventions in schools have been shown to cause negative labeling of individuals, stigmatization, and unhelpful peer-to-peer knowledge exchange [9]. These consequences could not be described as ''untoward medical occurrences'' but could be considered relevant to the evaluation of an intervention's benefits and harms.

Another problem in defining harm as adverse events in BCI trials is the potential for large numbers of events unrelated to the intervention to be recorded, impacting on trial efficiency and resources. This is particularly pertinent in populations with high frequency adverse events clearly unrelated to the trial intervention, for example, elderly people [14] or populations frequently hospitalized [15].

This scoping review was undertaken as part of a wider project [16] that aimed to develop recommendations on how to record harms in BCI RCTs. Although CONSORT harms provides detailed recommendations on the reporting of harms in RCTs, two key issues remain unclear to trialists: (1) How to decide what harms might be expected from a BCI? and (2) How to make decisions on what harms to

[1] Adverse event: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have causal relationship with this treatment. Serious adverse event: An adverse event that at any dose results in death or is life-threatening (requires hospitalization or prolongation of existing hospitalizations, results in persistent or significant disability/incapacity, or is a congenital abnormality/birth defect).

What is new?

Key findings

- Behaviour change interventions can cause harm.
- This scoping review identified and collated categories and proposed mechanisms of harms from behaviour change interventions, as well as methods and general recommendations on identifying and recording harms.

What this adds to what was known?

- Recording harms in RCTs has been found to be poor and inconsistent.
- This scoping review identified literature which may guide researchers on how to identify and record harms in randomised controlled trials of behaviour change interventions.

What is the implication and what should change now?

- Findings from this scoping review will be included in forthcoming recommendations on how to record harms in behaviour change interventions.
- Proportionate and transparent approaches to recording harms in randomised controlled trials of behaviour change interventions are required.

record in a BCI trial so that trials are run efficiently. Experienced researchers involved in designing and implementing trials were interviewed as part of the wider project [16] and reported that they found recording harms in BCI trials complex and confusing [17].

A range of literature on recording harms from BCIs exists across multiple disciplines, but this has not yet been collated and considered in the context of RCTs of BCIs. This scoping review aimed to examine the extent, range, and nature of literature on this topic area [16], descriptively summarize findings and provide an overview of the evidence [16,18].

2. Methods

Arksey and O'Malley's five-stage framework for scoping reviews was followed [18]. An iterative approach was used within our scoping review such as refinement of study selection and data charting during the review process, as recommended by Arksey and O'Malley [18] and in reviews conducted on research methods [19].

A protocol developed for the wider project includes details of the scoping review [16] and was approved by a Project Steering Committee, who advised during the project including the scoping review. As is often the case with scoping reviews, changes were made to the protocol during the review, and these are detailed in Appendix A. This scoping review adheres to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews reporting guideline [20].

2.1. Stage 1: identifying the research question

This scoping review aimed to identify literature that describes categories, definitions, or mechanisms of harms from BCIs, methods of identifying plausible harms, and recommendations for recording harms. In addition, the review aimed to identify and describe examples of harms caused by BCIs.

2.2. Stage 2: identifying relevant articles

Three electronic databases (MEDLINE, PsycINFO, and CINAHL) were searched in October 2021 from their inception with no publication time limit restrictions (see Appendix B for search strategy). Results were limited to articles written in English and using human subjects. Reference list checking and citation searching was performed on included articles. Citation searching was limited to the first 250 citations on Google Scholar.

2.3. Stage 3: article selection

As it can be necessary for scoping reviews, selection criteria were set a priori and refined once the reviewers were familiar with the literature [18]. Details of refinements are provided in Appendix A.

2.3.1. Behavior change interventions

Articles were considered for inclusion if they discussed a BCI. We defined BCIs as interventions which intend to modify behavior, for example, psychological therapies or a public health or lifestyle intervention such as weight management. Medical interventions, which we defined as drugs, procedures, for example, surgery or devices, were excluded. Multicomponent interventions might include both medical interventions and BCIs, and these were also excluded.

2.3.2. Study design

All study designs were considered, including empirical research, literature reviews, editorials, and opinion pieces where they could be applied to recording harms within RCTs. There is a dearth of RCT evidence on this topic area; hence, other study designs were included.

2.3.3. Phenomena of interest

Articles had to describe (1) categories or mechanisms or definitions of harms, (2) recommendations or methods of

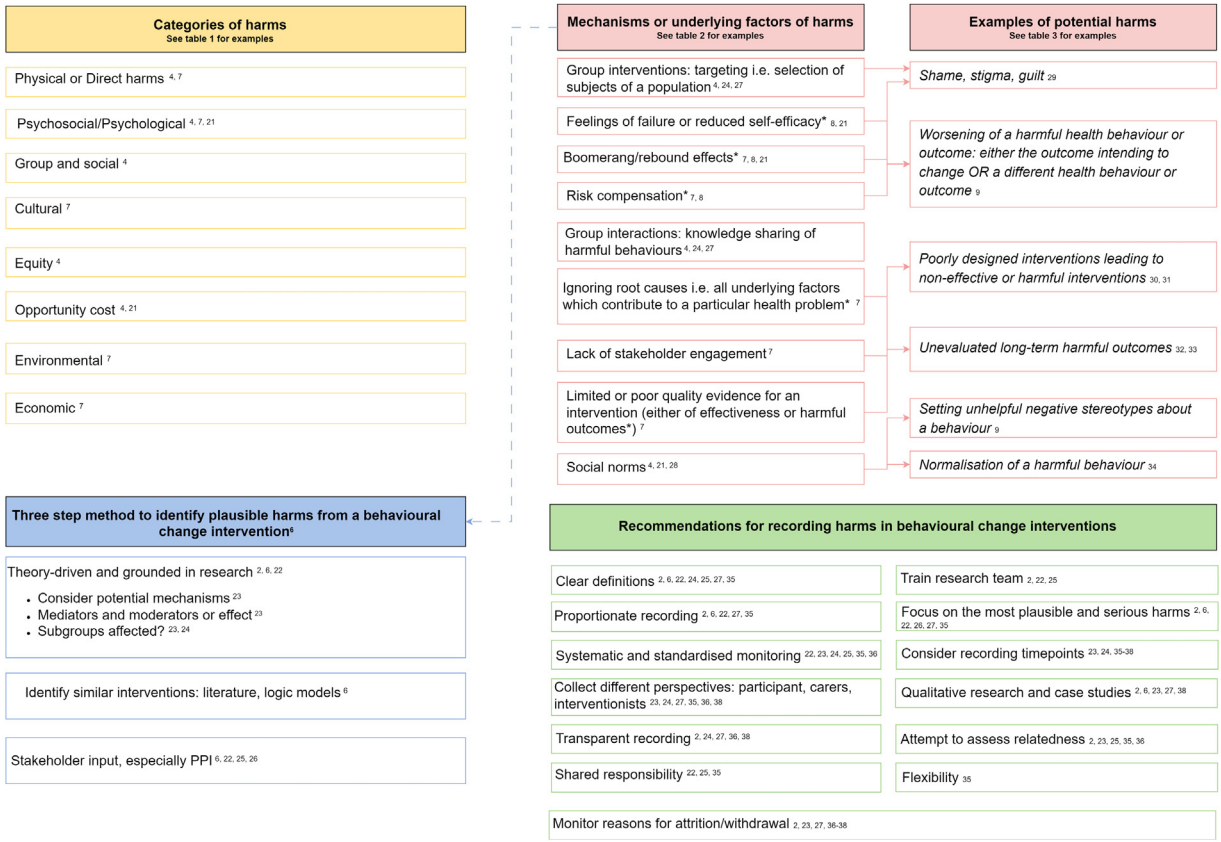

Fig. 1. Thematic map of the literature. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.) [2,4,6–9,21–31,33,35–42]

harms recording, or (3) examples of harms within specific BCIs. We considered harm wider than the ICH GCP definitions[2], and considered harm defined as per the CONSORT harms extension[3].

2.3.4. Selection process

One reviewer (any of S.H.K., D.P., or C.M.) examined title, abstract, and full texts against the inclusion criteria above. This is a complex and gray area. Therefore, reviewers met frequently to hold formative discussions on queries at full-text level about article selection, for example, to agree whether an intervention was a BCI or if the article included one of the phenomena of interest. When all reviewers had completed the selection process, a sample of articles at title level (10%) was independently checked by another reviewer.

2.3.5. Refinement of selection criteria

Study selection was iterative as is recommended in scoping reviews and reviews on research methods [18,19]. Modifications to selection criteria were made once reviewers were familiar with the literature and are described in Appendix A. Articles excluded because of refinements to study selection criteria are presented in Appendix C.

2.4. Stage 4: charting the data

Data charting was iterative in nature due to the range of concepts in the literature [19]. Data were charted by one reviewer (S.H.K.) and checked by another reviewer (D.P.). Quality appraisal was not undertaken, as is typically the case in scoping reviews [18]. Data were charted separately for (1) the thematic review and (2) the examples of harms in specific BCIs.

[2] Adverse event: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have causal relationship with this treatment. Serious adverse event: An adverse event that at any dose results in death or is life-threatening (requires hospitalization or prolongation of existing hospitalizations, results in persistent or significant disability/incapacity, or is a congenital abnormality/birth defect).

[3] The totality of possible adverse consequences of an intervention or therapy; they are the direct opposite of benefits, against which they must be compared.

For the thematic review, an initial data charting form was designed (Appendix D). Following initial data charting, five themes were identified, and data charted for each theme. The themes were general recommendations on harms recording, categories of harms, methods to identify harms, mechanisms of harm, and definitions of harms.

For the examples of harms from specific BCIs, the following data were charted: population, intervention, study design, and details of the harms.

2.5. Stage 5: collating, summarizing, and reporting the results

Insights from the literature within the thematic review were described by four themes: categories of harm, mechanisms of harm, methods for harms recording, and general recommendations on recording harms. Data for the fifth theme, definitions of harms, were tabulated (Appendix E).

Data for each of the four themes were collated and subthemes identified. See Appendix D for subthemes and description of their refinement and data collation. A thematic map of the literature (Fig. 1) was produced which visually presented the themes and subthemes and how these related to each other (as proposed by D.P. and S.H.K.). The project steering committee reviewed Fig. 1. Data were tabulated on the examples of harms from specific BCIs (Appendix F).

3. Results

3.1. Characteristics of included articles

The Preferred Reporting Items for Systematic reviews and Meta-Analyses flow diagram (Fig. 2) summarizes study identification including reasons for exclusion at full text. A total of 37 articles were included, published between 2005 and 2022, with the research based in 11 countries. Twelve articles were from the United States, 12 articles from the United Kingdom, five articles from Germany, and eight from the rest of the world. The 37 articles were divided into the two subreviews: (1) A thematic review (19/37 articles) which describes the data on categories, definitions or mechanisms of harm, or methods or recommendations for harms recording, and we report the results separately. (2) Examples of specific BCIs (18/37 articles). Fifteen articles could not be obtained by our library; details of these articles can be found in Appendix G.

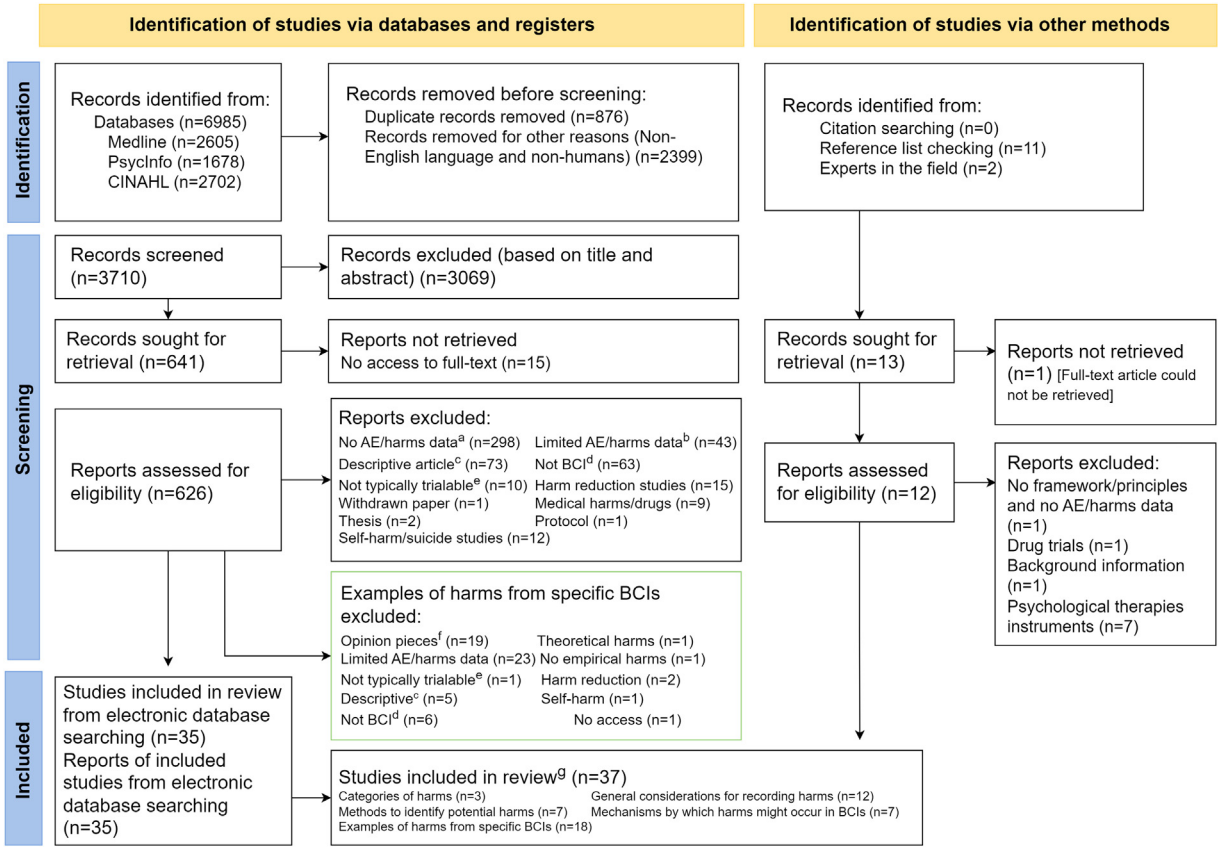

Fig. 2. PRISMA diagram and study flow. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

3.2. Thematic review

Nineteen of 37 of the articles were included in the 'thematic review' and are summarized in Appendix H. Most articles (n = 14) were discussion or opinion pieces [2,4,6,8,21–25,27,28,35,38,39], three of which reported on harms recording in a case study of a trial [22,25,35]. Four were literature reviews [7,36,37,40]. One article evaluated an instrument used to measure adverse events of psychological treatments but also provided discussion and opinion on defining and recording harm so was included [38]. One article reported on a workshop and provided recommendations to mitigate unintended consequences [26]. Public health, health communication, psychological therapies, health psychology, and general BCIs were discussed in these articles.

Fig. 1 presents a thematic map of the 19 studies which contributed to the thematic review.

Three articles described categories of harms [4,7,21]. Twelve articles provided recommendations for recording harms in BCI trials [2,6,22–27,35–38] and seven articles discussed mechanisms by which harms might occur in BCIs [4,7,8,21,24,27,28]. One study described a method (the ''Dark logic model approach'') to identify potential harms from BCIs [6] and aspects of this method were supported by six other articles [2,22,24–26,35].

3.2.1. Categories of harms

Three articles proposed categories of harm which were synthesized to provide a comprehensive list of eight potential harms from BCIs. Table 1 provides a description and example for each category of harm. Apart from physical or direct harms, and some psychological or psychosocial harms, events within the categories in Table 2 might not be considered as harms under the ICH GCP

Table 1. Categories of harm identified in the literature

Categories	Definition	Examples of each category
Physical or direct harms [4,7]	*A harm occurring to the physical structure of a person associated with an intervention/''desired health outcomes may have directly harmful effects''*	Obesity public health interventions increased cigarette smoking and growth failures in low socio-economic children [29]. Injury risk from sports programs [4].
Psychosocial/Psychological [4,7,21]	*''A harm involving injury or damage to both psychological and social aspects and may involve the connection between social conditions and mental health''*	Stigmatization, victimization, body dissatisfaction, and lowered self-esteem in children following obesity interventions [33,41]. Health campaigns can cause worry or guilt impacting on wellbeing, as well as the target health behaviors themselves [21,33].
Group and social [4]	*Group-based interventions may unintentionally cause harms by singling out a particular subset of the population, or by the effects of bringing them together/negative impacts at the level of social norms or perceptions may also occur*	Group interventions have been shown to worsen outcomes by grouping like-minded individuals together allowing knowledge exchange, for example, antisocial behavior and drug use [4].
Cultural [7]	*''Any damage to a population's 'way of life', which includes language, arts and sciences, spirituality, social activity, and interactions''.*	Allen-Scott [7] provide an example for a cultural harm, where disclosure of HIV status may lead to increased trust/intimacy between partners and lead to more unprotected sex [42]. This might be considered a cultural harm on the basis of damage to way of life relating to ''social activity and interactions''. We are not aware of any other examples of cultural harms.
Opportunity cost [4,21]	*''Potential benefits which may be forgone as a result of committing resources to ineffective or less effective interventions, or to less serious public health problems''*	Lorenc et al. [4] note it is hard to identify such harms.
Environmental [7]	*''Damage or injury to the circumstances, objects, or conditions by which one is surrounded.''*	Limited examples in literature. Allen-Scott [7] reports on one study where there is evidence for direct harms of road transport, but limited evidence on indirect health impacts (such as air quality and climate change) [34].
Economic [7]	*''Damage that relates to production, distribution, and consumption of goods and services.''*	The roll-out of a vaccine in a population when the long-term effects are not known could result in a waste of the resources of the government and private companies [32].
Equity [4]	*Worsening of existing health inequalities*	Population-level interventions such as media smoking cessation have sometimes worsened health inequalities, that is, privileged groups have benefited more than disadvantaged groups [4].

Table 2. Mechanisms of harms described in the literature

Mechanism name	Description	Example
Risk compensation [8]	Individuals who improve one health behavior may then pick up a different behavior, often unhealthier or negative, to compensate.	*One who has given up smoking may drink more alcohol to compensate, or vice versa. One who has started to exercise more may overeat.*
Boomerang/rebound effects [7,8,21]	The attempt to modify a behavior can lead to that behavior worsening, that is, opposite intended effect.	*An individual who intends to eat less may end up overeating or bingeing.*
Group interventions: targeting [4,24,27]	Group-based interventions may cause harms by unintentionally isolating or stigmatizing a specific group within a population.	*Groups may be stigmatized, or even divided. School children taken out of the classroom for an intervention may feel stigmatized or embarrassed* [7,9].
Group interactions: knowledge exchange [4,24,27]	Harmful health behaviors can be shared by grouping individuals together described as 'maladaptive learning' [27].	*People may come together into groups and learn behaviors that they would not have known otherwise,* for example, *antisocial behavior* [7].
Social norms [4,21,28]	Interventions may also have negative impacts at the level of social norms or perceptions, which may contribute to setting negative stereotypes of a behavior, or negative behaviors may be normalised.	*The normalization of negative health behaviors,* for example, *messages such as 'Nine of 10 people eat less than the recommended 200 grams of vegetables and two pieces of fruit a day' may suggest that being unhealthy is normal. Setting negative stereotypes,* for example, *promoting bicycle helmet use may exaggerate the perception of risk of injury when cycling, and therefore reduce cycling rates* [34].
Feelings of failure or inability/self-efficacy [8,21]	An individual may feel like they have an inability or reduced self-efficacy when a behavior change intervention fails. This can lead to feelings of shame, stigma, and guilt and/or boomerang or rebound effects	*Failure in a weight management intervention may cause shame, stigma, guilt, and even affect self-esteem, which can therefore cause overeating or bingeing, potentially worsening the initial behaviors it was aiming to change* [29].
Ignoring root causes [7]	Root causes are underlying social or environmental conditions that affect behavior and potentially influence risk of injury and disease.	*Obesity interventions that work by stigmatizing the target population are based on the concept that obesity is a modifiable risk factor suggest that individuals can control their condition, take responsibility for their health, and are to blame for their condition* [7]. *It is important for these types of interventions to consider all the causative factors and social and environmental determinants of a condition, which may be beyond the individual's control to change, for example, location of facilities or green space to exercise or access to shops which sell healthy produce.*
Lack of stakeholder engagement [7]	Interventions that do not engage with the target population mean that important knowledge transfer is overlooked. The intervention may not have considered complex societal, environmental, and biological influences, and compound the effects of ignoring root causes.	*Studies have found an association with increased risk of sexually transmitted diseases and pregnancy* [43], *as well as increased stigma, discrimination, and victimization occurred in interventions that did not engage with the target population, such as those aiming to treat and prevent HIV* [44] *and public health policies aiming to tackle obesity* [45].
Limited and poor-quality evidence [7]	Interventions without empirical evidence examining its effectiveness and harmfulness in both the short and long term can lead to unexpected harmful consequences.	*Some public health interventions aiming to tackle obesity have limited evidence on its long-term physical and psychosocial effects* (eg, *reduced self-esteem, body dissatisfaction, and dietary restriction)* [7].

definition of harm [13], highlighting the need to consider other definitions of harm such as the CONSORT harms extension [12].

3.2.2. *Mechanisms of harms*

Seven articles proposed nine mechanisms or underlying factors by which harms might occur from BCIs (Table 2). Three mechanisms (risk compensation,

boomerang/rebound effects, and knowledge exchange of harmful behaviors in group interventions) were identified as mechanisms that could result in *worsening of a health outcome or behavior*, either the intended behavior for change or another health outcome or behavior. For example, group interventions might target specific individuals, and this selection of a subset of a population might lead to harms such as shame, stigma, and guilt.

Feelings of failure or lack of self-efficacy could also lead to shame, stigma, and guilt. Where individuals believe their health is different to that described in health communication messages or their health is not improving despite their taking part in an intervention to improve their health, feelings such as failure or shame could have the subsequence of worsening the intended health behavior targeted by an intervention.

3.2.3. Method to identify plausible harms from a behavioral change intervention

The Dark Logic model approach was proposed as a way to identify plausible harms [6]. Although the method was proposed for use in public health interventions, six articles from other clinical disciplines supported aspects of this method (Fig. 1). The first step described in this method is to *theorize harms* [2,6,22], which includes considering potential mechanisms by which harms might occur [6,23], mediators and moderators of effect [23], and whether particular subgroups might be affected [24,23]. The second stage is to *examine the literature* for evidence of harms from similar interventions [6]. The third step is to *consult all relevant stakeholders*, including patient and public involvement, for their perspectives on what potential harms (and their importance) might be possible from a BCI [6,22,25,26].

Table 3. Three examples of harms from specific behavioral change interventions (See Appendix F for more examples)

Population	Intervention	Study design	Harms
CBT therapists [46]	Cognitive Behavior Therapy	Semistandardized interviews with therapists delivering CBT Fischer Symptom Checklist Unwanted Events-Adverse Treatment Reactions Checklist	- Therapists reported 372 Unwanted Events* (UEs) in 98 patients and side effects (SEs) in 43 patients - Unwanted events related to treatment were found in 43%, such as 'negative wellbeing/distress' (27%), 'worsening of symptoms' (9%), and 'strains in family relations' (6%) - 21% patients suffered from severe or very severe SEs - A close and supportive therapeutic relationship can cause reduced self-efficacy and dependency
Adult depression [47]	Internet-based guided self-help	Individual participant data meta-analysis	Education significantly moderated effects on symptom deterioration. Those with low education display higher risk for deterioration than those with higher education, as the self-help manuals tend to require advanced reading comprehension. This in turn may create feelings of hopelessness and decrease self-efficacy.
Deprived neighbourhoods in England [48]	Area-based health policy targeting deprived areas which prioritized the promotion of physical activity, improved existing physical activity facilities, and built new ones that cater for the local community	Ethnography interviews and survey	Adverse intervention effects that further disadvantaged the already deprived community I) 'Inequity drift': new facilities used more by 'affluent outsiders', not the intended population; 35.14% decrease in use by local people was found over an 8-yr period ii) Triple disadvantage: participants felt 'doubly disadvantaged', geographically/socially, as well as being individually marginalized and excluded. This intervention made them feel even more disadvantaged.

3.2.4. Recommendations for recording harms in behavioral change interventions

Thirteen recommendations on how to record harms within BCI evaluations were discussed in 12 articles [2,6,22−27,35−38]. The recommendations are depicted in Fig. 1. More detail about each of the recommendations can be found in Appendix I.

3.3. Examples of harm identified in specific interventions

Eighteen of the 37 articles described examples of harms from specific behavioral change interventions (Appendix F). Interventions included psychotherapy, cognitive behavioral therapy, other psychological treatments, meditation, mindfulness, social and peer support, social and emotional learning, public health policy, health communication messages or campaigns, and obesity prevention strategies. Table 3 describes three examples.

Seven of the 18 articles were qualitative studies [9,10,46,48−51], three systematic or literature reviews [29,52,53], three randomized study design [54−56], two surveys [57,58], one uncontrolled trial [59], one field experiment [60], and one individual patient data meta-analysis [47]. Since most evidence is from non-RCT study designs, there may be limitations as to whether the harms were caused by the intervention under study. There were few articles reporting RCTs. However, the 18 articles included appear to provide some evidence of harms occurrence in BCIs. The aim of describing these examples is not to prove that harm has been caused in these cases but rather stimulate discussion that harm may be possible.

4. Discussion

This scoping review identified (1) eight categories of potential harms which may arise from BCIs, for example, physical, psychological; (2) nine mechanisms or underlying factors for harms, for example, risk compensation; (3) 13 recommendations for recording harms, for example, taking a proportionate approach by focusing on the most plausible and important harms; (4) the Dark Logic model approach [6] as a method to identify plausible harms; and (5) 18 articles demonstrated harms arising from specific interventions, for example, a peer support intervention in inflammatory bowel disease caused distressing conversations which might lead to anxiety and confrontation with a possible negative future.

This review was purposefully broad with respect to the types of BCIs we considered. Harm from BCIs has received attention over the last 10+ years within different clinical disciplines [2−4,6,7,24,27]. The review draws together learning from these different disciplines.

4.1. Strengths and limitations

This is the first scoping review to comprehensively collate and describe the literature on categories, definitions, and mechanisms of harms, as well as methods and recommendations of recording harms, in BCIs. There were three limitations. First, the search strategy was designed to identify articles with a focus on harms, and thus may not have been sensitive enough to identify harms mentioned as secondary outcomes in empirical research when identifying the examples of harms in BCIs. Reference list and citation searching, and contact with experts, reduced this risk and bibliographic saturation appeared to be reached as we started to find the same references repeatedly. Second, although examples of harms from specific interventions were identified, our search strategy was not designed for this purpose. The criteria for the final selection of articles were modified once familiar with the literature to identify compelling examples of harms in BCIs to illustrate this important concept. There are likely to be other examples which demonstrate harm arising from BCIs which were not identified by our search. Third, study identification and data charting processes may have been prone to bias. We acknowledge there may be subjectivity around interpreting the selection criteria, for example, whether the intervention qualified as a BCI, or if the article included one of the phenomena of interests, for example, recommendations for harms recording. It is possible that the backgrounds of the three reviewers (all of whom are involved in designing and/or implementing RCTs) might have affected the interpretation of the inclusion criteria during the article selection process. We mitigated for this by reviewer team discussions and calibration, 10% check on article inclusion, and involvement of a Project Steering Committee (details available in Appendix D).

4.2. Implications

The 18 examples which describe harm from specific BCIs counter the potential misconception that harms are not possible from these types of interventions. We hope they may stimulate discussion among research teams of BCI evaluations.

The categories and mechanisms of harms identified in this review demonstrate the importance of defining harm beyond definitions originally devised for pharmaceutical trials to ensure harms are not missed in BCI evaluations. For example, the CONSORT Harms extension defines harm as the "*totality of possible adverse consequences of an intervention or therapy.*" We also hope the categories and mechanisms of harm identified in this review could serve as prompts for research teams, and be reviewed for applicability to their BCI when an evaluation is planned.

The recommendations identified for harms recording are pragmatic, with an emphasis on proportionate and transparent harms recording. The evidence from the literature

supports a focus on recording the most plausible and serious harms as opposed to exhaustive and potentially inefficient recording of harms in BCI evaluations.

4.2.1. Future research

The CONSORT harms extension notes the importance of active rather than passive collection of harms data [11]. We did not actively look for this information in our 18 examples of harms within specific BCIs. Others have explored this within harms collection in drug trials [61]; it would be interesting to explore this in BCI trials.

5. Conclusion

BCIs can cause harm. This review identified categories and proposed mechanisms of harms, as well as methods and recommendations for identifying and recording harms in BCIs for inclusion in forthcoming recommendations.

CRediT authorship contribution statement

Diana Papaioannou: Writing − review & editing, Writing − original draft, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Sienna Hamer-Kiwacz:** Writing − review & editing, Project administration, Formal analysis, Data curation. **Cara Mooney:** Writing − review & editing, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Cindy Cooper:** Writing − review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Alicia O'Cathain:** Writing − review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Kirsty Sprange:** Writing − review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Gwenllian Moody:** Writing − original draft, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization.

Data availability

Data will be made available on request.

Declaration of competing interest

All authors have completed the declaration of interest statement and declare support from the organizations described above for the submitted work. There are no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years and no other relationships or activities that could appear to have influenced the submitted work.

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Supplementary data

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