BMJ Open

Comparison of different mobile health applications for intervention in children and adolescent with overweight: a protocol for systematic review with meta-analysis and trial sequential analysis

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To cite: Perego P, Rashid R, Gluud C, *et al*. Comparison of different mobile health applications for intervention in children and adolescent with overweight: a protocol for systematic review with meta-analysis and trial sequential analysis. *BMJ Open* 2020;**10**:e032570. doi:10.1136/bmjopen-2019-032570

► Prepublication history and additional material for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2019-032570).

Received 25 June 2019
Revised 07 July 2020
Accepted 12 August 2020

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ABSTRACT

Introduction Overweight in children is increasing worldwide. Innovative smartphone health applications (mHealth apps) have either sought to deliver single or multi-component interventions for the management of overweight in children. However, the clinical effects of these apps are poorly explored. The objective of the review will be to compare the benefits and harms of different categories of mHealth apps for intervention of overweight in children.

Methods and analysis We will include randomised clinical trials irrespective of publication type, year, status or language. Children and adolescents between 0 to 18 years will be referred to as children in the remaining part of the paper. Children with all degrees of overweight included obesity and morbidly obese in the remaining part of the paper will be referred to as overweight. We plan to classify different apps according to type of intervention, measurement device, coaching and reward system. The following databases will be used: Cochrane Library, Excerpta Medica database (Embase), PsycINFO, PubMed, IEEE Explore and Web of Science, CINAHL and LILACS. Primary outcomes will be body mass index z-score, quality of life and serious adverse event. Secondary outcomes will be body weight, self-efficacy, anxiety, depression and adverse event not considered serious. Study inclusion, data extraction and bias risk assessment will be conducted independently by at least two authors. We will assess the risk of bias through eight domains and control risks of random errors with Trial Sequential Analysis. The quality of the evidence will be assessed using Grading of Recommendations Assessment, Development and Evaluation Tool (GRADE).

Ethics and dissemination As the protocol is for a systematic reviews, we have not included any patient data and we do not require ethical approval. This review will be published in a peer-reviewed journal.

PROSPERO registration number CRD42019120266.

Strengths and limitations of this study

- This review aims to be the first systematic review to compare the benefits and harms of different mobile health applications interventions in children with overweight following Cochrane guidelines.
- A comprehensive search strategy will be used with a large number of databases searched, and only randomised controlled trials in children with overweight will be included.
- The review will perform meta-analysis, Trial Sequential Analysis and use the Grading of Recommendations Assessment, Development and Evaluation Tool.
- We expect high heterogeneity across studies which may lead to challenges in performing a meta-analysis.
- It is anticipated that many papers will not provide sufficient details on all variables of interest and will lead to reliance on communication with corresponding authors for additional information.

INTRODUCTION

The prevalence of overweight are increasing worldwide among children irrespective of socio-economic status.[1–3] By 2025 more than 260 million children aged 5 to 17 years may be overweight, including 91 million obese according to data from Global Burden of Disease collaborative for 2000 and 2013.[4 5] The International Task Force of Obesity produced age and gender specific cut-off for the definition of overweight and obesity in children.[6] Throughout this paper we will use the term overweight for all children with overweight including all levels of obesity.

These trends of increasing overweight will have long-term consequences on cardiovascular disease, insulin resistance, type 2 diabetes and cancer (endometrial, breast and colon), resulting in a significant burden on health services across the world.[4] Recently, there has been an exponential growth in connected

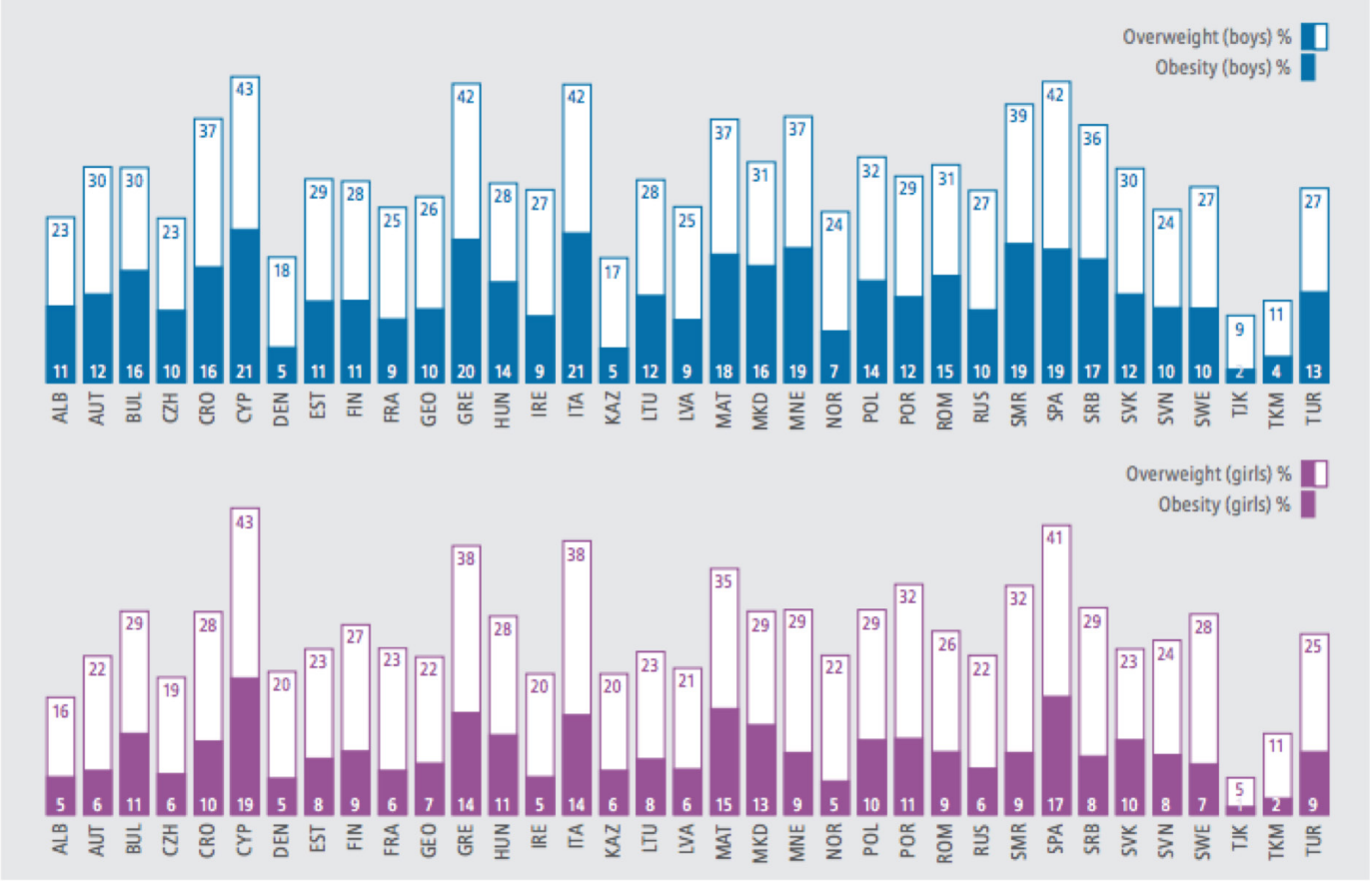

Figure 1 Overweight and obesity prevalence values based on WHO definition - COSI 2015 to 2017[4].

devices such as smartphones and tablets, supporting the development of new services. A plethora of software applications (apps) running on these devices are appearing on the market (figure 1). Health apps thus represent a huge area which potentially exploits the new paradigm of mHealth—Mobile Health. This refers to medicine and public health services supported by mobile devices. mHealth apps are commonly used in disease surveillance, treatment support and for educating children about prevention. However, despite the potential opportunities of mHealth, the main issue of these applications is the ability to engage the users to keep them motivated using the app, an aspect that is even more difficult if the users are young.[7]

Children are 'millennials' and 'natively digital' hence mobile technologies are potentially relevant and accessible tools for them, even in their health management. In this paper, we combined these two elements to analyse the mutual inter-relationships between the use of mobile systems to counteract overweight in children. Recent Cochrane reviews highlighted the benefits of multi-component interventions over single approach programmes on treating children with overweight. The authors, however, noted the paucity of good quality trials on multi-component interventions.[8–10]

mHealth apps

Smartphones increase the possibility to interact with people in a more personalised and tailored manner. They enable the building of platforms for adaptive interventions with visually appealing and engaging multimedia modalities which can be adjusted by the user based on their preferences.[11] mHealth apps have the ability to support children to achieve and maintain a healthy and sustainable lifestyle by supporting and strengthening their self-regulatory capacities.[12 13] They offer potential advantages over traditional face-to-face methods for delivering health-related interventions.[14–17] These include cost-effective dissemination, real-time data collection and feedback, lowered participant burden and flexible programme tailoring.[11]

No reviews to date, to our best knowledge, have specifically compared the efficacy of different categories of apps for interventions in children with overweight. In addition, while previous reviews have commented on the significant risk of bias in many studies, there has not been a consistency in including control of bias, the play of chance and assessing the quality with GRADE (Grading of Recommendations Assessment, Development and Evaluation) assessment in these reviews.[18–27]

Nutrition and diet apps represent a popular area of mHealth, offering the possibility of delivering behavioural change interventions for healthy eating and weight management in a scalable and cost-effective way. Use of commercial apps for paediatric weight management often fail to retain users because of a lack of theoretical

background and evidence-based content. However, mHealth apps that are more evidence-based are often found less engaging and popular among consumers.[28] Approaching the apps development process from a multidisciplinary, expert and user-centred design perspective is more likely to help overcome these limitations. They may also provide easier adoption and integration of nutritional education apps within primary and secondary care interventions.[29 30]

Such a process has been transitioned into health game apps where long-term use is dependent on providing easy and continual gaming access on both smartphones and tablets; offer games that can be personalised and are adaptable based on the child's interests; and maintain novelty and interest in the treatment over time.[31] This framework not only provides a benefit to the children involved, but also provides user data to the coaches, clinicians and health researchers involved in the child's treatment regime.[32] In addition, while many apps tended to focus either on nutrition or on physical activity, very few apps managed to adhere to or deliver a comprehensive overweight intervention for children due to a failure to support a spectrum of important target behaviours.[33]

The role of health researchers is therefore to evaluate the evidence base, efficacy and quality of different apps to ascertain whether these apps may have a part to play in the management of childhood overweight. In addition, assessment of the effect of the interventions have not been evaluated taking risks of bias, risks of random errors, type of control interventions, as well as the quality of evidence into account.[34]

Objective

The objective of the review will be to compare the benefits and harms of different categories of mHealth apps in interventions for overweight in children.

METHODS AND ANALYSIS

This work consists in a protocol for systematic review with meta-analysis and Trial Sequential Analysis with the aim to compare different typology of mobile health applications for intervention in children and adolescent with overweight. The paper is a continuation of the previous work[35] by the same authors in which the effectiveness of the use of applications in the prevention of obesity was studied. The methods section overlaps in part with our previous publication and with other Cochrane protocols and reviews, especially those following Cochrane methodology and using Trial Sequential Analysis which have common authors (C Gluud and J C Jakobsen).

Criteria for considering studies for this review

Types of studies

Randomised clinical trials irrespective of language, publication status, publication type or publication year up to July 2020 will be included in the review. Eligible studies which are not published in English will be translated using Google translate. Authors will be contacted to check if an English translation is available or to clarify any queries.

Types of participants

All children who are overweight (including all levels of obesity) up to 18 years of age (as defined earlier). Children with associated comorbidities, either physical or psychological secondary to overweight and obesity will be included. Children with causes of overweight due to medication such as steroids, or genetic disorders which are associated with overweight will be excluded.

Types of intervention

Any type of mHealth intervention using apps. There is no restriction as to how the app delivers the intervention or intervention duration or the type of electronic platform (smartphones, tablets and so on).

Types of outcomes

We will assess at baseline and then all outcomes at two further time points:

- End of intervention: as defined by trialist (primary time point of interest).
- Maximum follow-up.

Primary outcomes

- BMI z-score.
- Quality of life: as measured by any scale that has been validated for use in the target population.[36]
- Proportion of participants with at least one serious adverse event.[34]

Secondary outcomes

- Body weight measured in kg.
- Self-efficacy: as measured by a scale validated for use in children.
- Anxiety.
- Depression.
- Proportion of participants with at least one adverse event not considered serious.

Exploratory outcomes

- Body fat measured by bioimpedance or dual energy x-ray absorptiometry(DEXA), there having been good correlation between total body fat % by bioimpedance or DEXA ($r=0.87$, $p<0.001$).[37 38]
- Muscle mass (kg) via bioimpedance or DEXA.[37 38]
- Individual serious and non-serious adverse events.

Primary classification of mHealth apps

mHealth app interventions in overweight children cover a variety of typologies and related strategies. We have subsequently provided a systematic categorisation of these approaches for the systematic review. While appreciating that there will be some overlap in the app characteristics, the categorisation aims to identify the primary purpose or key component of the app in the intervention.

mHealth apps for overweight interventions usually target three different strategies—dietary change, increase

in physical activity and behavioural change.[39] Apps are mainly targeted to monitor or motivate small improvements such as steps per day, duration and intensity of physical activity or counting calories for nutrition. Indeed, behaviour or lifestyle (which also includes nutrition and physical activity) integrates data and suggests activities to the users in order to motivate them and try to change their behaviour.

Based on these three strategies, the apps can be then divided into different categories according to the main characteristic which is listed below as main bullet points:

- Presence of devices
  - Standalone mobile applications without connected devices for data gathering.
  - Mobile applications with devices (wearable devices, smart scales and so on).
- Coach
  - Mobile applications with a real human coach who interacts with the users (phone calls or messages).
  - Mobile applications with a virtual coach which provides suggestions to the users by means of gathered data.
  - Mobile application without a coach: this app only gets data and shows them to the users.
- Intervention (only if app includes a coach)
  - Mobile application with a standard reminder/suggestion, like the standard calendar notification.
  - Mobile application with an intelligent reminder/suggestion based on acquired data and habits.
  - Mobile application without a direct intervention.
- Reward
  - Mobile application with an intangible reward (virtual coins for in app purchase, emoji).
  - Mobile application with a tangible reward (money or discount coupons).[40]
  - Mobile application without a reward.

Further app categories can be described based on the connection of the application and how users can download it.

- Cloud and social connectivity.
- Mobile application connected with the cloud to store and process data.
- Standalone application without a connection.

Online supplemental table 1 shows this app classification with some examples and scientific papers related to them.

Search methods for identification of studies

Electronic searches

We will search the following databases:

- Cochrane Library.
- MEDLINE.
- Excerpta Medica database (Embase).
- PsycINFO.
- IEEE Explore.
- Web of Science (SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI, CCR-EXPANDED, IC).
- CINAHL.
- LILACS.

Searching other resources

- ClinicalTrials.gov (http://www.clinicaltrials.gov/)
- Google Scholar (https://scholar.google.com/)
- European Medicine Agency (http:// www.ema.europa.eu/ema/)
- United States Food and Drug Administration (www.fda.gov)
- Medicines and Healthcare Products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
- The WHO (www.who.int/)
- Global Obesity Forum (previously International Association for the study of Obesity) (www.iaso.org)
- European Association for the study of Obesity (EASO) (https://easo.org/)
- ICTRP Search Portal used in the search strategy

Keywords used in the search strategy

- Obesity
- Overweight
- Smartphone apps
- Health apps
- mHealth app
- Body mass index
- Weight gain
- Weight loss
- Hyperphagia
- Randomised controlled trial

Preliminary search strategy for MEDLINE is enclosed as online supplemental additional file 2.

Data collection and analysis

Selection of studies

The review will follow the recommendations in the Cochrane Handbook for Systematic Reviews of Interventions and according to Keus *et al* and Jakobsen *et al*.[41 42] The analyses will be performed using Review Manager[43] and Trial Sequential Analysis programme.[44]

Two authors (RR and PP) will independently screen titles and abstracts. They will retrieve all relevant full-text study/publication after which two authors will independently screen the full text in order to identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion. Trial selection will be displayed in an adapted flow diagram as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Online supplemental additional file 3 reports the PRISMA checklist.

Data extraction and management

Data extraction will be performed independently by at least two authors, who will both compare the extracted data. Disagreements will be resolved by a third author. We will assess duplicate publications and companion papers of a trial together to evaluate all available data simultaneously (maximise data extraction and correct

bias assessment). Trial authors will be contacted by email to request any additional data which may not have been reported sufficiently or at all in the publication. Review Manager software will be used to extract data.

Assessment of risk of bias in included studies

The risk of bias of every included trial will be evaluated independently by at least two authors. In case of any disagreement, discrepancies will be discussed with a third author and resolved by consensus. The risk of bias will be assessed using the Cochrane's 'Risk of bias' assessment tool[45 46] and the Cochrane Effective Practice and Organisation of Care Group's guidance.[46] We will evaluate the methodology in respect of:

- Random sequence generation.
- Allocation concealment.
- Blinding of participants and treatment providers.
- Blinding of outcome assessment.
- Incomplete outcome data.
- Selective outcome reporting.
- For profit bias.
- Overall risk of bias.

Classification of the trials will follow criteria defined in online supplemental file 4.

Meta-analysis

Both end-scores and change-from-baseline scores will be used to analyse continuous outcomes. If both end-scores and change-from-baseline scores are reported then only end-scores will be used. If only change-from-baseline scores are reported, these results together with end-scores will be analysed in the same meta-analyses.[45] Exploratory outcomes will be analysed using change-from-baseline scores.

Data will be meta-analysed by RevMan 5 statistical software. We will use Stata statistical software (Stata 2015) in case of zero event trials, where RevMan 5 zero event handling is insufficient.[47 48] We will report effect estimate using mean difference with 95% CIs.

Intervention effects will be assessed by both random-effects model meta-analyses and fixed-effect model meta-analyses,[27 44 49] using the more conservative point estimate of the two. Three primary outcomes will be examined with $p \leq 0.025$ being statistically significant. An eight-step procedure will be used to assess if the thresholds for significance are crossed. Five secondary outcomes will be examined with $p \leq 0.017$ being statistically significant.[38] The results of the exploratory outcomes will be considered hypothesis generating only.

Analysis of all included studies will be compared with a sensitivity analysis of studies at low risk of bias. If the results are similar, primary conclusions will be based at the time point closest to 12 months on the overall analysis. If the results differ, primary conclusions will be based on studies with a low risk of bias.

A table describing the types of serious adverse events in each trial will be provided.

Trial sequential analysis

Traditional meta-analysis runs the risk of random errors due to sparse data and repetitive testing of accumulating data when updating reviews. Trial Sequential Analysis will thus be used to analyse the outcomes in order to calculate the required information size and control the risks of type I errors and type II errors.[26 27 48]

For continuous outcomes, Trial Sequential Analysis will use the observed SD, a mean difference of the observed SD/2, an alpha of 2.5% for the three primary outcomes, an alpha of 1.67% for the five secondary outcomes and a beta of 10%, with adjustment for observed diversity.[50 51] Mean differences (MDs) and the standardised mean difference will be expressed with 95% CIs for continuous outcomes, as well as the Trial Sequential Analysis adjusted CIs for MDs. We intend to use the proportion in the control group and the diversity estimated in the meta-analysis to provide reliable results.

For dichotomous outcomes, Trial Sequential Analysis will use the proportion of participants with an outcome in the control group, a relative risk reduction of 20%, an alpha of 2.5% for primary outcomes, an alpha of 1.67% for secondary outcomes and a beta of 10%, with adjustment for observed diversity. We will calculate risk ratios with 95% CI for dichotomous outcomes, as well as Trial Sequential Analysis adjusted CIs.

Subgroup analyses

Subgroup analysis when analysing the primary outcomes will be performed as follows:

- Trials at high risk of bias trials compared to trials at low risk of bias trials.
- Trials stratified according to experimental interventions.
- Trials stratified according to weight status: overweight, obese or morbidly obese at the entry into the trial.[6]
- Trial stratified according to the control interventions.
- Complexity: trials with participants with no comorbidities compared to trials with participants pre-existing comorbidities.
- Trials in which the experimental intervention was evaluated by either the parents or the child after the treatment sessions had been delivered compared to trials in which the experimental intervention was not evaluated by either the parents or the child after the treatment sessions had been delivered.

We will use the formal test for subgroup interactions in Review Manager.[43]

Sensitivity analysis

To assess the potential impact of the missing data for dichotomous outcomes, we will perform the following sensitivity analyses:

- 'Best-worst-case' scenario: we will assume that all participants lost to follow-up in the experimental group had no serious adverse events, including not developing any psychiatric disease such as an eating disorder.

- 'Worst-best-case' scenario: all dropouts/participants lost from the experimental group, but none from the control group experienced the outcome, including all randomised participants in the denominator.

Statistical heterogeneity will be assessed by visual inspection of the forest plots and I^2 statistic values.[41] Underlying reasons behind statistical heterogeneity in meta-analyses will be investigated by assessing trial characteristics.

Summary of findings table

A summary of findings table using each of the prespecified primary and secondary outcomes will be reported using the GRADE considerations for studies which contribute data to the meta-analyses for the prespecified outcomes.[34 41 52–65] Methods and recommendations described in Chapter 8 (Section 8.5) and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions*[66] will be followed using GRADEpro software.

DISCUSSION

The objective of the review will be to compare the benefits and harms of different categories of mHealth apps for intervention of overweight in children. Currently, there are no systematic reviews which specifically compare the effects of different typology of mHealth apps to interventions in children with overweight. Previous systematic reviews in children have considered the efficacy of mobile health technologies more broadly in the role of weight management,[65] but none have provided comprehensive coverage of the benefits and harms of mHealth apps nor an in-depth study of the different types of apps. Hence, this evidence will hopefully help children and adolescents, their parents and health professionals to make informed treatment decisions. This review will also highlight any gaps in the evidence base of such interventions and in app structure which will help to shape the development and optimisation of future potential interventions and apps.

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Acknowledgements We would like to thank Sarah Louise Klingenberg, Information Specialist at the Copenhagen Trial Unit, Centre for Clinical Intervention Research, for her guidance and assistance on developing search methods keywords for search strategies.

Contributors IL, RR, PP, GA, CG and JCJ wrote the first draft of the protocol. PP, RR, IL, GA, JCJ and CG have revised the protocol. All authors read and approved the manuscript. IL is the guarantor for the review.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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Table 1 Classification of mhealth apps

Category	Name of the app	Authors	Year	Paper Title
App with device	Collective Intelligence	Addo et al	2013	Toward collective intelligence for fighting obesity
Standalone	iN Touch	Kim et al	2015	Youth-centered Design and Usage Results of the iN Touch Mobile Self-management Program for Overweight/Obesity
Real (Human)	Personal Wellness Coach	Asselin et al	2005	Implementation and evaluation of the personal wellness coach
Virtual	Move it move it	Frost et al	2012	We Like to Move It Move It!: Motivation and Parasocial Interaction
None	iN Touch	Kim et al	2015	Youth-centered Design and Usage Results of the iN Touch Mobile Self-management Program for Overweight/Obesity
Reminder	Txt2Bfit	Partridge et al	2015	Effectiveness of a mHealth Lifestyle Program With Telephone Support (TXT2BFiT) to Prevent Unhealthy Weight Gain in Young Adults: Randomized Controlled
Smart Suggestion	Teenagers and Digital Coaching	Kettunen et al	2018	Can Sport and Wellness Technology be My Personal Trainer?–Teenagers and Digital Coaching
None	MyFitnessPal	Levinson et al	2017	My Fitness Pal calorie tracker usage in the eating disorders
Intangible				**PEGASO DSAHBOARD (not published)
Tangible	Pegaso City	Caon et al	2016	PEGASO Companion: A Mobile App to Promote Healthy Lifestyles Among Adolescents
None	Fitbit for Obese	Yoost et al	2018	The Use of Fitbit Technology Among Rural Obese Adolescents
Connected	Collective Intelligence	Addo et al	2013	Toward collective intelligence for fighting obesity
Standalone	Personal Wellness Coach	Asselin et al	2005	Implementation and evaluation of the personal wellness coach

Search strategies for
Apps vs no apps
Preliminary searches performed 23 April 2019

Total number of records identified: **4494 records**
Number of duplicates excluded: **743 records**
Number of records in final list: **3751 records**

Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (2019, Issue 4) (546 hits)
#1 MeSH descriptor: [Obesity] explode all trees
#2 MeSH descriptor: [Hyperphagia] explode all trees
#3 MeSH descriptor: [Body Mass Index] explode all trees
#4 MeSH descriptor: [Weight Gain] explode all trees
#5 MeSH descriptor: [Weight Loss] explode all trees
#6 MeSH descriptor: [Anti-Obesity Agents] 1 tree(s) exploded
#7 (Pickwick* syndrom* or Prader willi syndrom* or obes* or adipos* or overweight* or 'over weight*' or overeat* or 'over eat*' or 'over feed*' or overfeed* or binge eating disorder* or 'fat overload' syndrom* or (weight and (gain or cycling or reduc* or loss or losing or maint* or decreas* or watch* or diet* or control*))).ti,ab
#8 #1 or #2 or #3 or #4 or #5 or #6 or #7
#9 MeSH descriptor: [Mobile Applications] explode all trees
#10 ((mobile or smartphone or telephone or virtual or digital or wellness or medical or dietary or physical activity or intervention or treatment or weight or calorie) and (app or coach or tracker))
#11 (m*health or mobile health or p*health or personal health or 'in touch' or txt2bfit or pegaso or fitbit or collective intelligence or 'move it' or myfitnesspal)
#12 #9 or #10 or #11
#13 #8 and #12

MEDLINE Ovid (1946 to April 2019) (510 hits)
1. exp Obesity/
2. exp Hyperphagia/
3. exp body mass index/
4. exp Weight Gain/
5. exp Weight Loss/
6. exp Anti-Obesity Agents/
7. (Pickwick* syndrom* or Prader willi syndrom* or obes* or adipos* or overweight* or 'over weight*' or overeat* or 'over eat*' or 'over feed*' or overfeed* or binge eating disorder* or 'fat overload' syndrom* or (weight and (gain or cycling or reduc* or loss or losing or maint* or decreas* or watch* or diet* or control*))).ti,ab.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp Mobile Applications/
10. ((mobile or smartphone or telephone or virtual or digital or wellness or medical or dietary or physical activity or intervention or treatment or weight or calorie) and (app or coach or tracker)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
11. (m*health or mobile health or p*health or personal health or 'in touch' or txt2bfit or pegaso or fitbit or collective intelligence or 'move it' or myfitnesspal).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
12. 9 or 10 or 11
13. 8 and 12
14. (random* or blind* or placebo* or meta-analys*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
15. 13 and 14

Embase Ovid (1974 to April 2019) (802 hits)
1. exp obesity/
2. exp hyperphagia/

3. exp body mass/
4. exp body weight gain/
5. exp body weight loss/
6. exp antiobesity agent/
7. (Pickwick* syndrom* or Prader willi syndrom* or obes* or adipos* or overweight* or 'over weight*' or overeat* or 'over eat*' or 'over feed*' or overfeed* or binge eating disorder* or 'fat overload' syndrom* or (weight and (gain or cycling or reduc* or loss or losing or maint* or decreas* or watch* or diet* or control*))).ti,ab.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp mobile application/
10. ((mobile or smartphone or telephone or virtual or digital or wellness or medical or dietary or physical activity or intervention or treatment or weight or calorie) and (app or coach or tracker)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
11. (m*health or mobile health or p*health or personal health or 'in touch' or txt2bfit or pegaso or fitbit or collective intelligence or 'move it' or myfitnesspal).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
12. 9 or 10 or 11
13. 8 and 12
14. (random* or blind* or placebo* or meta-analys*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]
15. 13 and 14

LILACS (Bireme; 1982 to April 2019) (24 hits)
(Pickwick$ syndrom$ or Prader willi syndrom$ or obes$ or adipos$ or overweight$ or 'over weight$' or overeat$ or 'over eat$' or 'over feed$' or overfeed$ or binge eating disorder$ or 'fat overload' syndrom$ or (weight and (gain or cycling or reduc$ or loss or losing or maint$ or decreas$ or watch$ or diet$ or control$))) [Words] and (((mobile or smartphone or telephone or virtual or digital or wellness or medical or dietary or physical activity or intervention or treatment or weight or calorie) and (app or coach or tracker)) or (m$health or mobile health or p$health or personal health or 'in touch' or txt2bfit or pegaso or fitbit or collective intelligence or 'move it' or myfitnesspal)) [Words]

Science Citation Index Expanded (SCI-EXPANDED) (1900 to April 2019), Social Sciences Citation Index (SSCI) (1956 to April 2019), Arts & Humanities Citation Index (A&HCI) (1975 to April 2019), Conference Proceedings Citation Index- Science (CPCI-S) (1990- April 2019), Conference Proceedings Citation Index- Social Science & Humanities (CPCI-SSH) (1990- April 2019), Emerging Sources Citation Index (ESCI) (2015 to April 2019), Web of Science Core Collection: Chemical Indexes Current Chemical Reactions (CCR-EXPANDED) (1986 to April 2019), Index Chemicus (IC) (1993 to April 2019) (Web of Science) (2612 hits)
#7 #6 AND #5
#6 TS=(random* or blind* or placebo* or meta-analys*)
#5 #4 AND #1
#4 #3 OR #2
#3 TS=(m*health or mobile health or p*health or personal health or 'in touch' or txt2bfit or pegaso or fitbit or collective intelligence or 'move it' or myfitnesspal)
#2 TS=((mobile or smartphone or telephone or virtual or digital or wellness or medical or dietary or physical activity or intervention or treatment or weight or calorie) and (app or coach or tracker))
#1 TS=(Pickwick* syndrom* or Prader willi syndrom* or obes* or adipos* or overweight* or 'over weight*' or overeat* or 'over eat*' or 'over feed*' or overfeed* or binge eating disorder* or 'fat overload' syndrom* or (weight and (gain or cycling or reduc* or loss or losing or maint* or decreas* or watch* or diet* or control*)))

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	n/a
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1

Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	16
Amendments			
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support			
Sources	#5a	Indicate sources of financial or other support for the review	16
Sponsor	#5b	Provide name for the review funder and / or sponsor	n/a
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	2
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10
Study records -	#11a	Describe the mechanism(s) that will be used to manage	11

data management		records and data throughout the review	
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	7
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	14
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	14
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	n/a
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	12

Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	14

Assessment of risk of bias in included studies

Random sequence generation

Low risk: If sequence generation was achieved using computer random number generator or a random number table. Drawing lots, tossing a coin, shuffling cards, and throwing dice were also considered adequate if performed by an independent adjudicator.

Unclear risk: If the method of randomisation was not specified, but the trial was still presented as being randomised.

High risk: If the allocation sequence is not randomised or only quasi-randomised. These trials will be excluded.

Allocation concealment

Low risk: If the allocation of patients was performed by a central independent unit, on-site locked computer or identical-looking numbered sealed envelopes.

Uncertain risk: If the trial was classified as randomised but the allocation concealment process was not described.

High risk: If the allocation sequence was familiar to the investigators who assigned participants.

Blinding of participants and treatment providers

Low risk: If the participants and the treatment providers were blinded to intervention allocation and this was described.

Uncertain risk: If the procedure of blinding was insufficiently described.

High risk: If blinding of participants and the treatment providers was not performed.

Blinding of outcome assessment

Low risk of bias: If it was mentioned that outcome assessors were blinded and this was described.

Uncertain risk of bias: If it was not mentioned if the outcome assessors in the trial were blinded or the extent of blinding was insufficiently described.

High risk of bias: If no blinding or incomplete blinding of outcome assessors was performed.

Incomplete outcome data

Low risk of bias: If missing data were unlikely to make treatment effects depart from plausible values. This could be either (1) there were no drop-outs or withdrawals for all outcomes, or (2) the numbers and reasons for the withdrawals and drop-outs for all outcomes were clearly stated and could be described as being similar to both groups. Generally, the trial is judged as at a low risk of bias due to incomplete outcome data if drop-outs are less than 5%. However, the 5% cut-off is not definitive.

Uncertain risk of bias: If there was insufficient information to assess whether missing data were likely to induce bias on the results.

High risk of bias: If the results were likely to be biased due to missing data either because the pattern of drop-outs could be described as being different in the two intervention groups or the trial used improper methods in dealing with the missing data (e.g. last observation carried forward).

Selective outcome reporting

Low risk of bias: If a protocol was published before or at the time the trial was begun and the outcomes specified in the protocol were reported on. If there is no protocol

or the protocol was published after the trial has begun, reporting of serious adverse events will grant the trial a grade of low risk of bias.

Uncertain risk of bias: If no protocol was published and the outcome of serious adverse events were not reported on.

High risk of bias: If the outcomes in the protocol were not reported on.

Other risks of bias

Low risk of bias: If the trial appears to be free of other components (for example, academic bias or for-profit bias) that could put it at risk of bias.

Unclear risk of bias: If the trial may or may not be free of other components that could put it at risk of bias.

High risk of bias: If there are other factors in the trial that could put it at risk of bias (for example, authors conducted trials on the same topic, for- profit bias, etc.).

Overall risk of bias

Low risk of bias: The trial will be classified as overall 'low risk of bias' only if all of the bias domains described in the above paragraphs are classified as 'low risk of bias'.

High risk of bias: The trial will be classified as 'high risk of bias' if any of the bias risk domains described in the above are classified as 'unclear' or 'high risk of bias'.

We will assess the domains 'blinding of outcome assessment', 'incomplete outcome data', and 'selective out- come reporting' for each outcome result. Thus, we can assess the bias risk for each outcome assessed in addition to each trial. Our primary conclusions will be based on the results of our primary outcome results with overall low risk of bias. Both our primary and secondary conclusions will be presented in the summary of findings tables.