How is the efficacy, safety and effectiveness of weight control and obesity management apps assessed? A systematic review

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Abstract

Background: In recent years there has been a rise in the use of Mobile Applications (Apps) to prevent and treat adult overweight/obesity since they can facilitate the tracking of physical and dietary patterns, provide recommendations and advice, and include motivation strategies to achieve personalized goals. However, evidence available on the efficacy, effectiveness and safety criteria used for assessing theses Apps is scarce.

Objective: To identify efficacy, safety and effectiveness criteria used to assess weight control, overweight and obesity management in Mobile health (mHealth) interventions through a systematic review.

Methods: PUBMED, PsycINFO, Scopus, UK Tripdatabase, Clinical Trials Register and the Cochrane library were browsed up to May 2018. All kinds of clinical studies were considered. Two independent reviewers assessed quality using SING criteria. Ratings were used to provide an overall score for each study (low, moderate or high). Data were synthesized in evidence tables.

Results: From 226 potentially relevant publications, only 21 studies were included. Of those, 11 (52%) were randomized control trials, 8 were one-single arm studies (38%) and 2 were controlled trials (10%). The studies were classified as low (10), high (6) and moderate (5) quality according SING criteria. All of them focused on efficacy, but none on effectiveness and safety.
In 8 studies the Apps were used as stand-alone interventions, the rest were multicomponent studies that included other tools for support such as sensors or web sites.
The main management tool included in the Apps was feedback messaging (18 Apps), followed by mechanisms of self-monitoring and setting goals (14 each one).
The majority of the studies selected considered weight/body mass index loss as the main outcome (15) followed by changes in physical activity (11) and diet (9). Regarding the outputs, the most reported were Usability/Adherence/Engagement (13), followed by Acceptability and Satisfaction (4 each one).

Conclusions: There is a remarkable heterogeneity among studies and most of them have methodological limitations which left considerable room for improvement regarding the quality of the studies. This research allows for the identification of relevant criteria to assess efficacy of weight control in overweight and obesity management mHealth interventions, but no information

about safety and effectiveness was found. Clinical Trial: The protocol was registered on PROSPERO (CRD42017056761) on 14 February 2017.

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Web-based and Mobile Health Interventions

How are efficacy, safety and effectiveness of weight control and obesity management mhealth interventions assessed? A systematic review

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ABSTRACT

Background: The use of apps to tackle overweight/obesity by tracking physical and dietary patterns, and providing recommendations and motivation strategies to achieve personalized goals has risen over recent years. However, evidence of the efficacy, effectiveness and safety of these apps is severely lacking.

Objective: To identify efficacy and safety and effectiveness criteria used to assess weight control, overweight and obesity management in Mobile health (mHealth) interventions through a systematic review.

Methods: PUBMED, PsycINFO, Scopus, UK Tripdatabase, Clinical Trials Register and the Cochrane library were surveyed up to May 2018. All types of clinical studies were considered. Two independent reviewers assessed quality using SING criteria. Ratings were used to provide an overall score for each study (low, moderate or high). Data were synthesized in evidence tables.

Results: From 233 potentially relevant publications, only 28 studies were included. Of these, 13 (46%) were randomized control trials, 11 were single arm studies (39%), 3 were non-randomized controlled trials (11%) and one study was a cluster-randomized trial (4%). The studies were classified as low (15), high (7) and moderate (6) quality according to SIGN criteria. All focused on efficacy, with only one trial mentioning safety and another one effectiveness. In 11 studies the apps were used as stand-alone interventions, the others were

multicomponent studies that included other tools for support such as sensors or web sites. The main management tool included in the apps was feedback messaging (24), followed by goal-setting mechanisms (20) and self-monitoring (19). The majority of studies took weight/body mass index loss as the main outcome (22) followed by changes in physical activity (14) and diet (12). Regarding outputs, Usability/Adherence/Engagement (17) were the most reported, followed by Satisfaction (7) and Acceptability (4).

Conclusions: There is a remarkable heterogeneity among these studies and the majority have methodological limitations that leave considerable room for improvement. Further research is required to identify all relevant criteria for assessing the efficacy of mHealth interventions in the management of overweight and obesity.

TRIAL REGISTRATION: The protocol was registered on PROSPERO (CRD42017056761) on 14 February 2017.

Keywords

mHealth; obesity; overweight; systematic review; evaluation; assessment

Introduction

Obesity and overweight are considered major public health concerns due to their high prevalence and association with various health complications including cardiovascular disease, type 2 diabetes and cancer [1,2]. As the aspects that influence overweight and obesity are diverse –comprising individual, genetic, and environmental factors– their prevention and treatment are also complex. In order to be successful multifactorial approaches are required, with diet and exercise plans reinforced with psychological therapy and behavioural change strategies [3].

In recent years we have witnessed a revolution in the use of apps within personal healthcare, as they are fast, flexible, handy, versatile, manageable and illustrative tools that can empower patients. Hence, Mobile health (mHealth) can play an important adjuvant role in the prevention and treatment of overweight/obesity by tracking physical activity, enabling the self-reporting of dietary patterns, providing recommendations to achieve healthier habits, guidance, advice, tips and motivational strategies to achieve personalized goals; all relevant aspects for the prevention and treatment of obesity, as recognized in numerous guidelines [3,4].–

The Global Observatory for eHealth of the World Health Organization (WHO) defines mHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” [5]. The management –and in some cases the prevention– of chronic diseases has been one focus in recent developments in both electronic and mobile Health (eHealth and mHealth) [6]. There are over 325.000 health apps on the market, with the most downloaded being those relating to physical activity and weight control: i.e., those that support a healthy lifestyle [7]. However, information on how the effectiveness, efficacy and safety of mHealth apps in overweight and obesity management is severely lacking. It is important to note that according to mhealth publishers over 53 % of their health apps portfolio available in 2015 were downloaded less than 5000 times [7]. Evidence of the efficacy of mHealth app strategies in improving chronic health and wellbeing is mixed; therefore, while some mHealth interventions show promise in supporting weight management [8,9] others do not [10,11]. Numerous efforts to address this challenging issue are underway and some aspects that may be linked to a lack of efficacy have been identified: these are, among others, the poor quality of many apps, a lack of guidance on the usefulness of an app, and a low level of support from health professionals, [12,13]. Should mHealth apps be rigorously evaluated to ensure they provide evidence-based effectiveness, safety and efficacy? Up to now, mHealth evaluation methodology has not deviated from customary methods (mainly Randomized Controlled Trials), despite claims that alternative, shorter and more inexpensive design methods are required [14].

There are several initiatives attempting to define how apps should be evaluated. However, all of these consider only partial aspects of evaluation [15]. Although medical regulatory bodies have not validated the safety and quality of these technologies, individuals have adopted mHealth devices as self-management aids, while medical professionals are often at a loss as to how to relate to them [16]. Due to this rapid consumer-based introduction to the world of patient health aids, mHealth solutions present unique and stakeholder-specific challenges to the medical environment. As patients, healthcare providers, administrators, authorities, and mHealth developers alike are operating without a clear direction, problems can arise, including the improper use of mHealth interventions by individuals, and the inability of medical systems to react due to a lack of technological and organizational support. Users and healthcare professionals should be aware of the quality of health apps they use or prescribe. The use of classic methodologies such as RCTs may not be the optimal procedure for evaluating all the dimensions of mHealth. Ideally, clinicians, health administrations and users need instruments that enable the evaluation of e-interventions as a whole. From a global perspective, these instruments should facilitate the process of verification, validation, impact assessment and certification that ought to be a requirement for all mHealth implementation.

This lack of rigorous evaluation is an increasing concern for health authorities. A number of recommendations to ensure a minimum quality of mHealth interventions have already been defined by the WHO Technical Evidence Review Group [17]. In addition, both the *Food and Drug Administration* [18][~~19~~] and the *European Commission* [19] have made several attempts to establish mHealth assessment and, where appropriate, certification criteria. However, in such a continuously evolving field it has been difficult to reach a consensus.

The aim of this paper is to undertake a systematic review of efficacy, safety and effectiveness assessment criteria in use, including both outputs and outcomes, to assess weight control, overweight and obesity management in mHealth interventions. These criteria will later be included in a tool for assessing mHealth interventions intended to manage overweight and obesity.

Methods

This systematic review was prospectively registered with PROSPERO under reg. no CRD42017056761 [20]. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was used as a guide for reporting this review [21] Due to the methodological and statistical heterogeneity of the included

studies, a descriptive approach was adopted in the research synthesis.

Eligibility criteria

Any trial that assessed the efficacy and/or safety and/or effectiveness of mHealth-based interventions for overweight or obesity management was considered. No restrictions in terms of target population were foreseen. We define efficacy as changes in lifestyles based on diet and physical activity in a controlled population; effectiveness in the general population; and safety as a lack of adverse effects resulting from mHealth interventions. Studies carried out with less than 10 individuals were excluded. We assessed the quality of trials according to the Scottish Intercollegiate Guidelines Network (SIGN) criteria [22]. Taking the objective of this review into consideration, all studies were included regardless of quality.

Information sources

A systematic search was conducted in the following databases: MEDLINE, EMBASE, PsycINFO, The Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL) UK trial database and Scopus. This survey was supplemented through the snowballing technique to identify relevant articles in the references of those returned by the search. A manual search was also conducted on the indices of the following publications: the *Journal of Medical Internet Research* (JMIR) and the *JMIR mHealth and uHealth*. The survey period included all articles published up to May 2018. All types of clinical studies published in English, French or Spanish were considered.

Search strategy

The search strategy included both controlled vocabulary and free-text terms. The terms used were: apps, mHealth, eHealth, overweight, obesity, efficacy, security, safety, effectiveness and evaluation (see Multimedia Appendix 1).

Study selection and data collection process

All identified references were imported into Mendeley (v1.18) and duplicates eliminated. A total of six researchers undertook the review process, which was conducted in two stages. First, each article identified was randomly assigned to two reviewers to independently review the title and abstract. Articles that met the inclusion

criteria were full-text reviewed and quality-assessed by two independent reviewers. In cases of disagreement, a third reviewer made the final decision. Study features and outcomes were entered into a database specifically designed for this review. Risk of bias was assessed according to SIGN codes for study assessment [22]. Those trials that were clearly of an adequate quality were graded as 'high or ++' (very low risk of bias) or 'moderate or +' (low risk of bias), while those of insufficient quality were graded as 'low or –' (high risk of bias).

Results

Selection of studies

A total of 233 potentially relevant publications (17 from a manual search) were identified as eligible. From these, 46 (19.7%) were identified as duplicates. From the remaining (187), only 92 (49.2%) were accepted for abstract review. Out of these, 44 (47.8%) were excluded for not following inclusion criteria. A full-text review was conducted on 48 studies. After peer-review, 30 articles corresponding to 28 different studies (62.5% from the total included for full-text review) were finally included in this non-quantitative review. The exclusion criteria were: published study protocols (n=8), out of scope studies that were not using an mHealth intervention (n=4) or those studies in which final outcomes were other than efficacy or safety (n=6) (Fig. 1) (see Multimedia Appendix 2).

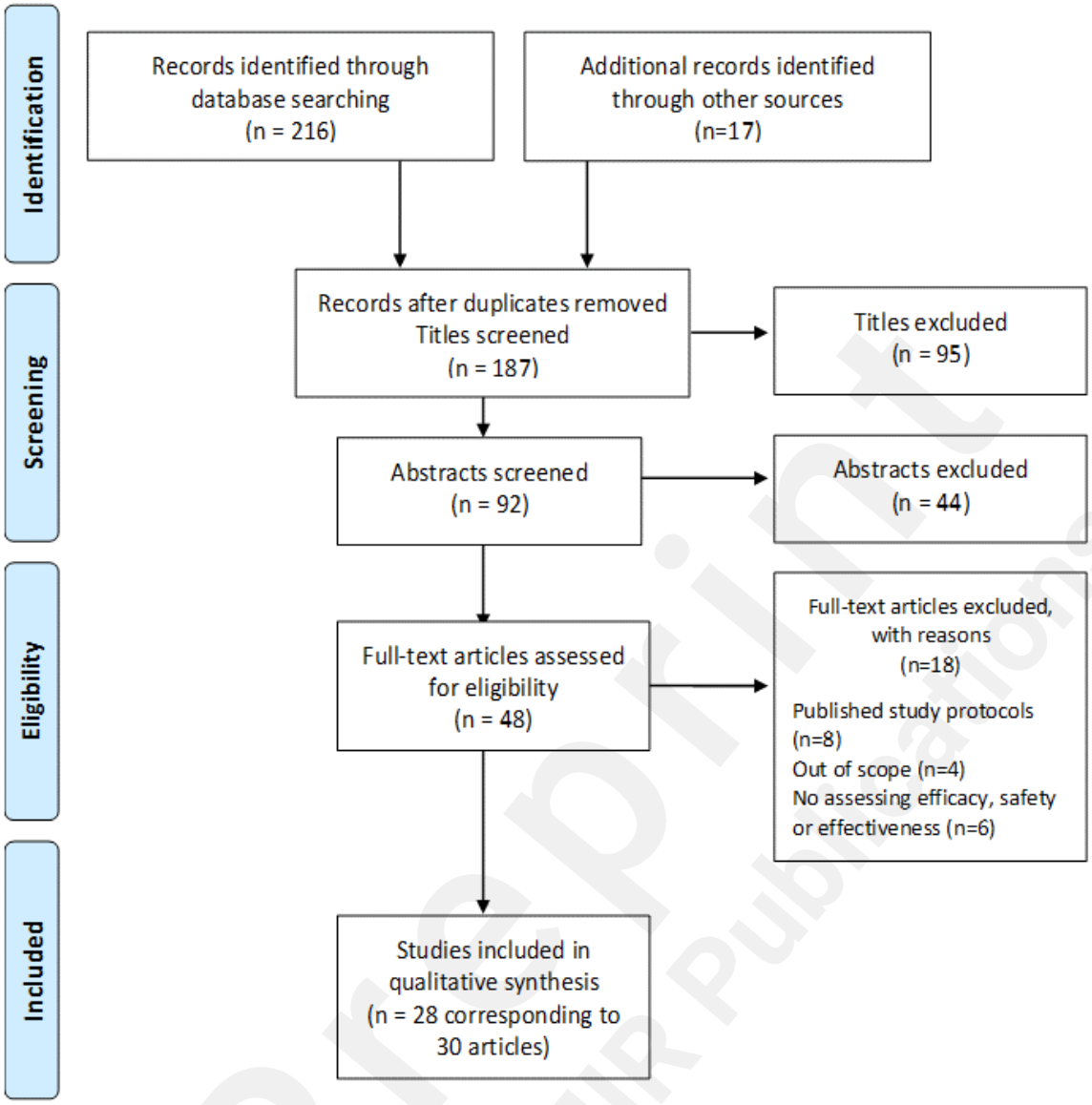

Fig. 1. PRISMA Flow diagram of selection of papers for inclusion in the review

The main characteristics of the 28 studies included are detailed in Table 1. Studies appear in alphabetical order of the first author within chronological years. All selected studies focus on efficacy; only one of them assesses effectiveness and one also focused on safety, although this was not the main outcome of the study.

Table 1: Characteristics of the Selected Studies

Ref	Design, (N)	Country	Population	Intervention	Quality	Limitations
2010 Lee [23]	CT[a] (2 groups), (36)	USA and Latin Amer	Sex: No Inf[b] Age: 28.2 (i) [c] 29.5 (c) [d] BMI[e]: 22.2 (i)	Efficacy of the SmartDiet App (6 weeks)	Moderate	No specifications about control conditions or randomization

		ica	22.3 (c)			method.
2013 Carter [24]	RCT[f] (3 groups), (128)	UK	Sex: 77% women Age: 42±9 BMI: 34±5	Efficacy in weight management intervention by My Meal Mate App. (6 months)	Low	Selection bias: motivated volunteers, different educational level according to randomization
2013 Thomas [25]	Single-arm pre-post (1 group), (20)	USA	Sex: 95% women Age: 53±1.9 BMI: 36.3±1.2	Efficacy of Daily Burn + Health-E-call app (24 weeks)	Low	Small sample size. Short-term effects (24 weeks). No control group. Potential motivational bias.
2014 Bond [26]	Single-arm pre-post (1 group), (30)	USA	Sex: 83% women Age: 47.5±13.5 BMI: 36.2±7.5	Efficacy of B-MOBILE App to reduce time spent in sedentary behaviour (4 weeks)	Low	Small sample size. Selection bias: volunteers Possible misclassification of sedentary behaviour by the armband sensor.
2014 Nollen [27]	RCT (2 groups), (51)	USA	Sex: women Age: 11.3±1.6 BMI: 23.7±5.7 Low-income, ethnic minority	Efficacy of MyPal A626 behavioral change in weight control (12 weeks)	Moderate	Small sample size. Too short to appreciate behavioral change.
2015 Block [28]	RCT (2 groups), (339)	USA	Sex: 31.27% woman. Age: 55±8.9 BMI: 31.2±4.4 Pre-diabetic patients	Efficacy of Alive-PD that provides tailored behavioural support (6 months)	High	Potential selection bias: study participants were relatively well-educated and mainly non-Hispanic white people.
2015 Finkelstein [29]	RCT (2 groups), (30)	USA	Sex: All women Age: 52±12 BMI: 37±6	Efficacy of mHealth intervention to increase physical activity (8 weeks)	Moderate	No information about recruitment. Randomized crossover design study.
2015 Fukuo	RCT (2	USA	Sex: 77% women	Diabetes Prevention	Moderate	Low number of participants.

ka [30]	groups), (61)		Age: 55.2±9.0 BMI: 33.3±6.0 48% were racial/ethnic minorities. Pre-diabetic condition.	Program (monitoring of weight, caloric intake and PA[g]), with reduced number face-to-face + home-based exercise program (5 months)		Selection bias: participants willing to use a mobile App and a pedometer.
2015 Martin [31]	RCT (2 groups), (48)	USA	Sex: 46% women Age: 58±8 BMI: 31±6 Patients with heart disease	Efficacy of a mActive intervention in PA performance (5 weeks)	Moderate	Limited size and scope. Different stages of the trial with different approaches when blinding participants.
2015 McCarroll [32]	Single-arm pre-post (1 group), (50)	USA	Sex: women Age: 58.4±10.3 BMI: 34.9±8.7 Overweight cancer survivors	Efficacy of nutrition and exercise counselling through LooseIt app (1 month)	Low	Small sample size. Non-controlled single arm trial. Low completion rate (70%).
2015 Oh [33]	RCT (2 groups), (422)	Korea	Sex: 46.7% (i) and 51.4% (c) women. Age: 46.78 (i) 50.35 (c) BMI: 29.42±3.53 (i) 29.40±3.39 (c)	Efficacy of SmartCare services in obese patients with metabolic syndrome. Safety was also assessed. (24 weeks)	High	Potential selection bias: higher educated participants were assigned to the intervention group despite random selection.
2015 Partridge [34], 2016 [35]	RCT (2 groups), (214)	Australia	Sex: 61% women Age: 27.7±4.9 BMI: 27.1±2.5	Efficacy and engagement with the mHealth program components of TXT2BFiT intervention. (3 months + 6 follow up months)	High	Results might have been biased since the sample was mostly well-educated and from high socioeconomic areas.

2015 Pretlow [36]	Single-arm pre-post (1 group), (43)	Australia	Sex: 65% women Age: 16±0.43 BMI: 0,98±0.0 mean percentile.	Efficacy of mHealth intervention for weight loss based on an addiction treatment approach (20 weeks)	Low	Small sample size. Non-controlled study. Selection bias: participants were selected if motivated; economic compensation proportional to completion. Low completion rate (63%).
2015 Naimark [37]	RCT (2 groups), (85)	Israel	Sex: 54% women Age: 47.9±12.3 BMI: 26.2±3.9	Efficacy of Web-based eBalance App for healthy people (14 weeks)	High	Good retention rate in both control and intervention group. Short length of the intervention.
2015 Spook [38]	Cluster Randomization Trial (2 groups), (501)	The Netherlands	Sex: 62.8% woman. Age: 17.28±1.3 BMI: 21.1±3.3 Secondary school students	Efficacy of Balance It, serious self-regulation game intervention (4 weeks)	Low	Very high dropout rates (72, 4%). Cluster randomized trial at school level. Short term intervention Self-reported outcomes
2015 Svetkey [39]	RCT (3 groups), (365)	USA	Sex: 69.6% women Age (mean): 29.4 BMI (mean): 35.2	Efficacy of App or Professional Coach intervention to lose weight (24 months)	High	No important limitations.
2016 Aschbrenner [40]	Single arm pre-post (1 group), (32)	USA	Sex: 56% women Age: 48.8±11.9 BMI: 37.7±7.9 Patients with serious mental illness.	Efficacy of lifestyle change intervention (Apps + wearable + Facebook) to reinforce physical activity and healthy eating (24 weeks)	Low	Non-controlled single-arm study. Small sample size.
2016	Single	Austr	Sex: All	Be positive –	Low	Single-Arm study,

Hutchesson [41]	arm pre-post (1 group), (18)	alia	women Age: 22.8±3.2 BMI: 27.3±1.6	Be health programme for weight loss (3 months)		non-controlled. Non-probabilistic selection of participants. Small sample.
2016 Jensen [42]	Single arm pre-post (1 group), (16)	USA	Sex: 75% women Age: 14.29±1.1 BMI: 1.85±0.1	Efficacy of smartphone assisted adolescent behavioural weight control intervention with DailyBurn App (24 weeks)	Low	Small sample. Heterogeneity of participants. No control group.
2016 Lee [43]	Single arm pre-post (1 group), (20)	Korea	Sex: 33% women Age: 20-40 BMI: 23 – 25: 38.5% 25 – 30: 33.0% >30: 28.5%	Develop and test efficacy of With U App and social network off-line and on-line (4 weeks)	Low	Single-Arm study, non-controlled. No information about selection of participants. Small sample.
2016 Michaelides [44]	Single arm pre-post (1 group), (43)	USA	Sex: 86% women Age: 51.5±8.3 BMI: 35.5±6 Hyperglycemic (HbA1c[h] between 5.7% and 6.4%)	Efficacy of a novel mobile Diabetes Prevention Program delivery platform with human coaching (24 weeks)	Low	No control group. Small sample.
2016 Quintiliani [45]	Single arm pre-post (1 group), (10)	USA	Sex: all women Age: 59±6 Overweight breast cancer survivors 50% ethnic minority group	Mobile Health-Supported Behavioral Counselling Intervention for weight control (10 weeks)	Low	Single-Arm study, non-controlled. Small sample. Ownership of a Smartphone as well as home WIFI was required.
2016 Willey [46]	Single arm pre-post (1 group), (10)	USA	Sex: All women Age: 43.5 (35-49) BMI: 31.6 (range 27.2-	Efficacy of YouPlus Health coaching platform (12 weeks)	Low	Single-Arm study, non-controlled. Small sample.

			36.4).			
2017 Gomez-Marcos [47] and 2018 Garcia-Ortiz [48]	RCT (2 groups), [833, 415 (i) 418(c)]	Spain	Sex: 60.0% (i) 64.1 (c) women Age: 51.4±12.1 (i) 52.3±12.0 (c) BMI: 28.1±5.1 (i) and 27.6±4.6 (c)	mHealth intervention to improve the adherence to a Mediterranean diet and increase of PA (3 months)	High	No blinding due to the nature of the intervention. Dropout rate above 10%. No guarantee other Apps on PA or diet were not used.
2017 He [49]	CT (2 groups), (15.310)	China	Sex: 40.5% (i) and 66.5% (c) woman. Age: 35.1±8.5 (i) and 39.0±9.5 (c) BMI: No inf.	Effectiveness of We Chat intervention (6 months)	Low	No randomization. Self-reported outcomes. High dropout rates in the intervention group.
2017 Mummah [50]	RCT (2 groups), (135)	USA	Sex: 62.2% women Age: 39.4±6.7 (i) 40.3±5.8 (c) BMI: 28 – 40	Efficacy of Vegethon App to increase vegetable consumption (5 weeks)	High	No relevant limitations.
2017 Mao [51]	CT (2 groups), [1012, 763 (i) 249(c)]	USA	Sex: 66.7% women Age: 44.6±11.3 BMI: 33.5±0.2	Efficacy of Health coaching service (Vida Health App) + wireless scale, pedometer, and blood pressure management (5 months)	Low	No randomization. Retrospective data. Self-reported data. Lack of a true control group.
2018 Hurkmans [52]	RCT (4 groups), (102)	Belgium	Sex: 84% (i) 75% (c) women Age: 44±12.4 (i) 45±10.2 (c) BMI: 32±2.0	Efficacy in weight loss and other outcomes of an App intervention, alone or combined with face-to-face coaching (3 months)	Moderate	Small sample. Possible bias in data collection. Self-reported outcomes.

[a] CT = non-randomized controlled trial

[b] No Inf = no information available
[c] (i) = intervention group
[d] (c) = control group
[e] BMI = body mass index (always measured as kg/m^2)
[f] RCT=randomized control trial
[g] PA= physical activity
[h] HbA1c= Haemoglobine A1c

Thirteen of the studies (46.4%) are RCTs, one is a cluster-randomized trial [38], three are non-randomized controlled trials, and the remainder (11) single-arm trials. Two of the RCTs include more than one intervention. Carter et al. [24] studied the efficacy of a smartphone app or website in self-monitored weight management and Hurkmans et al. [52] compared one stand-alone app intervention with face-to-face and blended interventions. All studies compare pre and post outcomes to analyse the intervention's efficacy. According to SIGN criteria the majority of studies are of low (15) or moderate (6) quality, with only 7 studies reaching high quality. A low quality rating most often resulted from small sample size, inadequate length of study or possible selection and information bias.

The number of participants ranged from 10 to 1012, but most studies (17) covered less than 100 people. One trial [49] had 15.310 participants, but the majority (83%) remained non-active during the intervention. Most studies had a majority of adult women; in 6 all participants were women. There are also 4 studies targeted at children and teens. Most trials were targeted at people with overweight or obesity but no other health condition: exceptions targeted people with a severe mental illness [40], heart disease [31], type 2 diabetes [44] or pre-diabetes [28,31], cancer survivors [32,45] and people with metabolic syndrome [33].

Apart from one 24-month trial [39], the studies were conducted over short periods of time, ranging from 3 weeks to 6 months. The countries where the studies were carried out were the USA (17), Australia (3), Korea (2), and the UK, Belgium, Spain, The Netherlands, China and Israel.

Elements included in the mHealth interventions

In regard to the specificities of mHealth interventions (Table 2), only 10 out of 28 (39.3%) focused on a specific stand-alone app, with the majority addressing multicomponent interventions –including armband sensors, pedometers, wireless scales and other monitoring devices, or websites– for weight management, intended to

increase physical activity, reduce sedentary habits and/or improve dietary patterns. The most common elements included in the trials were the receiving of feedback messages (24 studies out of 28, 85.7%), setting of goals (20) and self-monitoring (19). These feedback messages could be personalized reminders, recommendations based on the self-monitoring, standard counselling or health coach counselling through the app and/or a more synchronic intervention. New elements have been introduced to mHealth interventions in recent years, such as gamification [23,28,38,44,49], entertainment aspects [28,29,36,38,41], and peer contact through community blogs [34] or virtual teams [28] on social networks [36,40,43] such as Facebook [40,43,52] and We Chat [49]. It is worth mentioning that only specific frameworks were mentioned when defining strategies for behavioural change, such as the transtheoretical model of behaviour change for TXT2BFiT [34] and CITY [39], intervention and Control Systems Theory for eBalance App [37], self-regulation theory for Balance It intervention [38], and increasing adherence, such as Mechanics-Dynamics-Aesthetics for With U App [43]. Social Cognitive Theory is the one most often refferred to, by the Vegethon app [50], LooseIt app [32] and Alive-PD [28] for which several other frameworks were also considered: behavioural economics, positive psychology and the theory of planned behaviour. One study was based on the Diabetes Prevention Program [53] and LookAHEAD (Action for Health in Diabetes) trials [54]. One study was based on an addiction treatment approach [36].

Table 2: Elements included in the mHealth interventions of the selected studies

mHealth intervention	Components	Elements included						
		Education	Self-monitor	Setting goals	Feed-back	Gamifi-cation	Peers Network	Enter-tainment
SmartDiet [23]	MyPage App DietGame App		+	+		+		
Health-E-call [25]	DailyBurn app + Health-E-call app	+	+	+	+			
My Meal Mate [24]	Stand-alone App		+	+	+			
B-mobile [26]	Aka App + Armband sensor			+	+			
Stand-alone App [27]	Stand-alone App		+	+	+			
Multicomponent [36]	App Face-to-face sessions Phone meetings		+	+	+		+	+
LooseIt [32]	Stand-alone app		+	+	+			
Multicomponent [29]	Fitbit App Website		+	+	+			
Diabetes	App	+	+		+			+

Prevention Program (mDPP) [30]	Pedometer Face-to-face sessions							
mActive [31]	Fitbug App Armband sensor			+	+			
TXT2BFiT [34,35]	eVIP, ePass, eSIYP Apps My Message Media Website	+	+	+	+		+	
eBalance [37]	Stand-alone App		+		+			
Cell Phone Intervention for You (CITY) [39]	Stand-alone App Personal coach			+			+	
SmartCare [33]	App Body composition monitors Pedometers	+	+	+	+			
Alive-PD [28]	App Web e-mail Interactive voice response Phone calls	+	+	+	+	+	+	+
Balance It [38]	Stand-alone App	+		+	+	+		+
Multicomponent [40]	FitBit App Facebook		+	+	+		+	
Be Positive Be Healthe [41]	Website App		+	+	+		+	+
DailyBurn [42]	Stand-alone App	+	+	+	+			
With U [43]	App Facebook			+			+	
Noom [44]	App Personal Health Coach	+	+		+	+		
Multicomponent [45]	Fitbit Aria Scale Fitbit Flex Tel and face-to-face counseling	+			+			
YouPlus Health [46]	Stand-alone App	+	+		+			
Evident II [47,48]	App Pedometer		+		+			

Vegethon [50]	Stand-alone App			+	+		+	
Vida Health [51]	App Scale Pedometer Blood pressure cuff	+			+			
We Chat [49]	Stand-alone App	+			+	+	+	
B-slim [52]	Stand-alone App	+	+	+			+	

Output tools and measures

Although their main aim is to measure the efficacy of mHealth interventions, most of the selected studies also measure other outputs that might be relevant to determine primary outcome measures (23 out of 28, 82.14%). Table 3 shows the outputs and the main tools used to measure them.

Table 3: Output tools and results from the selected studies

Output	Ref	Tool	Result
Acceptability	Carter 2013 [24]	Evaluation Survey	- At 6 months 63.2% of smartphone participants were satisfied or very satisfied compared with 50.0% in the diary group and 42.1% in the website group (*P* = .05).
	Finkelstein 2015 [29]	Focus Group	- A majority of the participants expressed high acceptance of the mobile App and indicated willingness to use it in the future.
	Hutchesson 2016 [41]-	Evaluation survey Objective data tracking participants' performance	- Mean satisfaction was 3.4 (maximum of 5). - There were 22 posts to the discussion forum. - One-third of participants (n = 6) added at least one post to the discussion forum.
	Quintiliani 2016 [45]	Open questions survey	- Nine out of 10 participants responded that it is "very likely" that they would participate again or recommend the program to others. - However, 7 out of 10 participants responded that it is "somewhat unlikely" or "not at all likely" that they would participate again if they had to pay for the program.
Usability/	Lee 2010	Data	- The mean number of transmissions was 12.4 per

Adherence/ Engagement	[23]	tracking	patient.
	Carter 2013 [24]	Intervention use	- Intervention usage was highest in the smartphone group: mean of 92±67 days completed compared with 29±39 days in the diary group and 35±44 days in the website group[a].
	Thomas 2013 [25]	Data tracking	- Participants adhered to self-monitoring at 90.8 ± 3.3% at 12 weeks and 84.9 ± 4.0 at 24 weeks[a]. Participants were considered to be adhering if recording daily body weight and at least 3 meals or food intake per day.
	Nollen 2014 [27]	Time- and date-tracking	- Girls used the program on 63% of days, responded to 42% of prompts, and earned an average of 23.9 songs.
	McCarroll 2015 [32]	Data tracking	- Patients who failed to log more than 3-days in a row: 30% (15 participants).
	Spook 2015 [38]	Data tracking	- Only 27.6% of the participants used the intervention.
	Partridge 2016 [35]	Semi-structured telephone interviews On-line surveys Data tracking	- Smartphone apps, resources and community blog used by less than 25 % of participants. - Coaching calls, text messages and emails were described as helpful to achieving goals.
	Safran 2015 [37]	Data tracking Google Analytics	- The mean frequency of use was 2.7±1.9 days a week (95% CI 2.2-3.2). The average period of use was 7.8±4.3 weeks. - Self-monitoring declined over the study period. At the end of 14 weeks, 27% of users were still active on the App. Average duration of visits was 7.5±0.9 minutes and average number of pages per visit was 6.2 ± 0.6[a].
	Svetkey 2015 [39]	Data tracking	- Participants interacted with the study App an average of 4.6 times/day in the first 6 months and 0.7 times/day in the final year.
	Block 2015 [28]	Data tracking	- Interaction was a median of 17 of the 24 weeks (Interquartile range 14). In all, 87.1% of the participants interacted with the program in 4 or more of the 24 weeks.
	Aschbrenner 2016 [40]	Usage of Fitbit and private Facebook group	- All (100%) of the participants used the Fitbit and 76% used the private Facebook group.
	Jensen 2016 [42]	Self-monitoring	- On average, participants monitored at least 2 meals on 48.3% of days during the in-person intervention

			(12 weeks). - Participants monitored at least 2 meals on 16.6% of the available days during the electronic-only intervention period (12 weeks).
	Lee 2016 [43]	System Usability Scale [55]	- 63 out of 100 points indicated slightly low usability (threshold is 68).
	Michaelides 2016 [44]	Data tracking	- Meals per week logged 15.3±5.1. - Minutes per week of exercise 141.6±112.9. - Number of group comments per week 2.1±1.8[a].
	Quintiliani 2016 [45]	Data tracking	- Mean number of responses was 60±13, for responding to text messages; 64±7 for recording a step measurement; 45±24 for recording a weight measurement; and 43±19 for recording a sleep measurement, out of a possible 70 [a].
	Willey 2016 [46]	Data tracking	- 100% completed tutorials. - N questions asked 16 – 276 in discussion. - N questions answered 100 – 276 in forums. - Mean weekly opens: 5.1 – 18.4.
	Garcia-Ortiz 2018 [48]	Number of recorded days on the device.	- 100% completed tutorials. - The median use of the App was 67 days. - 56.8% participants in the intervention group had high App adherence (more than 60 days). - Participants with low adherence were younger (49.5 vs 52.9 years), and there was a higher proportion of smokers.
Satisfaction	Thomas 2013 [25]	Likert scale	- All participants endorsed the maximum rating for satisfaction.
	Oh 2015 [33]	Likert scale	- In a 1-5 scale satisfaction was 3.92±0.85[a]
	Pretlow 2015 [36]	Likert scale	- In a 1-5 scale satisfaction was 3.11±0.15[a]
	Safran 2015 [37]	Ad-hoc questionnaire based on [56]	- Moderate to very high recommendation for the App 93%. - Satisfaction on a scale of 1-10 was 7.3 ± 1.9[a].
	Jensen 2016 [42]	Client Satisfaction standardized Questionnaire [57] Semi structured interviews.	- Score: 20.3 out of 22. - Most described the intervention favourably (86%), reporting that the intervention “worked well” or was “very helpful.” - Participants enjoyed learning about nutrition and exercise (33%) and being able to meet with an expert to have their questions answered (20%). - Half of participants found the DailyBurn App to be “tedious” and “difficult to use” (53%).
	Lee 2016 [43]	Lim and Kang scale [58]	- Before/After 48.7/54.2 points ($P < .01$).
	Mao 2017	Rating of	- Only 43.6% of participants in the intervention group

	[51]	the App (out of 10)	rated their satisfaction, score = 9.8±0.7[a].
Motivation to weight loss	Bond 2014 [26]	Likert Scale	- 90% of participants endorsed either a 4 (n=11) or 5 (n=17) indicating that the App intervention significantly increased their motivation.
	Lee 2016 [43]	Jung [59] and Yu [60] scales	- A score of 15.4±1.4 out of a possible 20[a].
Intention to continue	Safran 2015 [37]	Self-report questionnaire based on [61]	- Control group: no significant change (*P* = .16) but in the App group, from 76 ± 7.5 to 79 ± 8.7 at the end of the study (*P* = .04)[a].
Perceived support	Aschbrenner 2016 [40]	Social Provisions Scale [62]	- Weight loss significantly associated with perceived peer-group support (r= .59, *P* = .02).
	Quintiliani 2016 [45]	Ad hoc Perceived Stress Scale	- Reductions in fatigue, loss of control in eating and perceived stress of -1.8±0.8,- 0.5±0.7 and -0.4±3.3, respectively[a].

[a] values are expressed as mean±SD

Acceptability

Four studies out of 28 (14.3%) attempted to measure participants' acceptance of the intervention, using mixed methods (survey, focus groups, data performance tracking) [24,29,41,45]. Results show that participants are willing to participate in these interventions, although receiving a smartphone [24] or doing it on a voluntary basis are elements that should be considered [45].

Usability / adherence / engagement

These three dimensions have been considered together, as the main analysis strategies used (data tracking and surveys) integrate all three aspects. Only one study used a validated questionnaire to assess usability [43], the System Usability Scale questionnaire. Several studies measured these outputs through different strategies, mainly data tracking. Results are very heterogeneous and depend on the study design and the specificities of each intervention.

Satisfaction

Only seven studies analyzed the satisfaction rate of users [25,33,36,37,42,43,51], with three of these using standardized validated tools [56–58]. Results show that most of the participants were very satisfied with the

intervention, although a few considered the app too tedious to use.

Motivation to lose weight and to continue the intervention

Few studies [26,43] addressed continued motivation to lose weight after the intervention [37]. Only one of these [43] used a previously validated methodology, while the other two studies assessed motivation or intention to continue through a Likert-scale [26] and self-reported questionnaires [37]. Results showed increases in users' motivations and in the adoption of a positive attitude towards managing their overweight or obesity.

Perceived peer support

Out of the seven studies dealing with peer support, only two attempted to assess the perception of this support [40,45]. Both showed a high perceived importance of peer support in reducing stress associated with the intervention.

Outcome tools and measures

The end-point outcomes of the selected studies were: reduction of weight and Body Mass Index (BMI), of fat mass and waist and hip circumferences; changes in dietary habits, physical activity and screen time patterns; biochemical measurements and blood pressure.

Table 4: Main Outcome results from the selected studies

Outcome	Ref	Tool	Result
Weight reduction / BMI	Lee 2010 [23]	Bioelectrical impedance analysis with InBody 720	- Reduction in weight in intervention group 1.9 (ss)[a] and 0.5kg in control group (ns)[b].
	Carter 2013 [24]	Weight by Watchers 8958U Body Analyser Scale portable. Height portable stadiometer to the nearest 0.1 cm	- Weight reduction: ITT[c] mean in App group –4.6 kg (ss); in the diary group –2.9 kg (ss) and in the website group –1.3 kg (ns). - BMI[d] ITT mean change at 6 months –1.6 kg/m^2 (ss) in the App group; –1.0 kg/m^2 (ss) in the diary group; and –0.5 kg/m^2 (ns). Difference (P < .01). - Follow-up weight between the groups at 6 months (ss).
	Thomas 2013 [25]	Digital scale and	- Weight reduction: 10.9±1.1kg[e].

	stadiometer.	
Block 2015 [28]	Non specified	- Weight loss: intervention group 3.26 (95%CI -3.26 to -3.25) kg; control group 1.26 (95% CI -1.27 to -1.26) kg (P < .001). - BMI loss: intervention group 1.05 (95CI -1.06 to -1.05); control group 0.9 (95 CI -0.39 to -0.38) (P < .001).
Fukuoka 2015 [30]	Tanita WB-110 digital electronic scale and conventional stadiometer	- Intervention group lost an average of 6.2 kg between baseline and 5-month follow-up compared to control group who gained 0.3 kg (P < 0.001). - Mean BMI decreased in the intervention group with almost no change among controls (P < 0.001).
McCarroll 2015 [32]	499KI. Health O Meter ® Professional Digital Column Scale, Neosho MO	- BMI decreased from 34.9±8.7 kg/m^2 versus 33.9±8.4 kg/m^2 (P < 0.0006)[e].
Oh 2015 [33]	Bioelectrical impedance analysis with InBody U20	- Weight reduction was 2.21±3.60 Kg in the intervention group and 0.77±2.77 kg in the control group (P < 0.001)[e]. - BMI reduction was 0.86±1.32 kg/m^2 and 0.33±1.05 kg/m^2 (P < 0.001)[e].
Pretlow 2015 [36]	Health-O-meter stadiometer (Continental Scale Corp., Bridgeveiw, IL) and self-calibrating 500-pound capacity Faribanks digital scale.	- Males 13.3 % over BMI. - Females 3,8 % over BMI.
Safran 2015 [37]	Portable digital scale (Beurer GmbH & Co. KG, Germany).	- The App users lost more weight compared to the control group: -1.4±0.4kg versus -0.13±0.4kg (P =.03)[e]. - The mean BMI change was -0.5±0.1 kg/m^2 in the App group, but only -0.03±0.1kg/m^2 in the control group (P = .03)[e].
Svetkey 2015 [39]	Weight: in high-quality calibrated digital scale.	- All groups lost weight at 6, 12 and 24 months. No significant differences between the 3 groups at 24 months. - Personal coach greatest mean weight loss at 6 (-3.1kg) and 12 months (-2.1kg) than App [6 months=-2.2kg, 12 months=-2.1kg] (P < 0.05).
Aschbren	Weight loss	- Weight loss: 72% participants lost weight, 28%

ner 2016 [40]	calculated as the proportion that achieved clinically significant reduction of ≥5% from baseline weight.	achieving clinically significant weight loss. - Weight loss of 7.8±12 kg[e]. - BMI decrease of 1.3±2.0 kg/m^2 [e].
Hutchesson 2016 [41]	Bioelectrical impedance analysis with InBody 720	- Reduction in weight in 1.5±2.4kg; (*P* =.02)[e].
Jensen 2016 [42]	Weight with a digital scale (Seca 869) and height using a portable stadiometer (Seca 217)	- Significant reduction in weight during face-to-face + App intervention (*P* = .04). - Back to initial weight after only online intervention.
Lee 2016 [43]	Bioelectrical impedance analysis with InBody 720	- Weight measures: Before: 80.2kg, After 79.3kg (*P* < .001).
Michaelides 2016 [44]	No information	- Weight loss at 16 and 24 weeks was significant. - A rate of 64% of completers losing over 5% body weight.
Partridge 2016 [35]	Self-reported data Standardized protocol for weight and height [63]	- No difference between self-reported or measured data. - Weight loss: 2.2 kg (0.8-3.6) *P* < .01. - BMI loss: 0.5 13 kg/m2 (0.1-1.0) *P* = .02.
Quintiliani 2016 [45]	Scale not specified	- Mean weight reduction in 1.5±3.5 kg[e].
Willey 2016 [46]	Single calibrated scale at physician's office	- Reduction of 6.1kg representing 7.3% of baseline *P* < .01.
Gomez-Marcos 2017 [47]	Seca 770 scale, Seca 222 height rod.	- At 3 months, there were no significant differences in baseline measurements in the overall population.
He 2017 [49]	Auto-reported weight	- No significant decrease of weights between groups: control group 1.78±2.96 and intervention group 2.09±3.43 kg[e].
Mao 2017	Weight via a	- Mean weight loss at 4 months in intervention group:

	[51]	Bluetooth scale. Some participants self-enter data	-3.2±0.2 kg ($P < .001$)[e].
	Hurkmans 2018 [52]	Scale not specified	- Significantly more participants in three intervention groups lost at least 5% of their body weight compared with the control group. - More participants in the combined group lost 5% or more compared with the App group (19%, $P = .06$). - In the conventional group, App group, and combined group, BMI decreased significantly ($P < .01$, $P < .01$, and $P <0.001$, respectively).
Fat mass reduction	Lee 2010 [23]	Bioelectrical impedance analysis with InBody 720	- Reduction of fat mass in 1.2 kg (ss) (i) and 0.5kg (ns) (c).
	Oh 2015 [33]	Bioelectrical impedance analysis with InBody U20	- Statistically significant reduction $P =.001$.
	Lee 2016 [43]	Bioelectrical impedance analysis with InBody 720	- Before: 31.34%, after 30.87% (ns).
Waist circumference reduction	Block 2015 [28]	No information	- Mean reduction intervention group 4.56 (95CI -4.69 to -4.43); control group 2.22 (95CI -2.36 to -2.09) ($P < .001$).
	McCarroll 2015 [32]	Spring-loaded tape measure (Gulick Tape Measure, Perform Better)	- Before: 108.1±14.9 cm; after intervention: 103.7±15.1 cm. ($P < .0006$).
	Safran 2015 [37]	Measured on the navel	- No changes between intervention and control group were measured.
	Hutchesson 2016 [41]	A 0.1 cm using a non-extensible steel tape measure	- Reduction in waist circumference 0.7±1.4cm ($P = .04$)[e].
	Lee 2016 [43]	Bioelectrical impedance analysis with InBody 720	- Waist circumference before: 33.5cm, after 33.3cm ($P < .05$). - Waist-hip ratio before: 0.91, after 0.90. (ns).
	Willey 2016 [46]	Physician's office	- Reduction by 7.2cm or 6.6% from baseline $P < .01$.
	He 2017	Auto-reported	- No significant decrease: control group 2.39±3.91

	[49]	measure	and intervention group 2.74±4.48 cm[e].
	Hurkmans 2018 [52]	Inelastic tape perpendicularly to the long axis of the body while the subject stood balanced on feet.	- Within the conventional group, App group, and combined group, a decrease in metabolic risk factors was found, but this change was not significant (*P* = .12, *P* = .15, and *P* = .23). It does not specify which other outcomes are considered together with waist circumference.
Hip circumference	Fukuoka 2015 [30]	Standard protocol (not specified)	- The intervention group had greater reductions in hip circumference (*P* < .001).
Change in Physical Activities	Bond 2014 [26]	SenseWear Mini Armband monitor	- Percent time spent in both light- (*P* < .05) and moderate-to-vigorous (*P* < .01) PA[f] was significantly increased compared to baseline.
	Finkelstein 2015 [29]	Step count measured via Fitbit	- Higher average daily number of steps in intervention group (ns). - Inactivity lower in intervention group (25%) compared to control group (30%) (*P* < .02).
	Fukuoka 2015 [30]	Omron Active Style Pro HJA-350IT pedometer	- Intervention participants increased their daily step count by a mean of 2,551 (4,712) steps (a 38% increase) compared with a mean decrease of 734 (3,308) steps (an 11% decrease) among controls (*P* = .02).
	Martin 2015 [31]	Data tracking by accelerometer	- Control participants attained a mean of 616 fewer steps/day (6% decrease). Intervention participants increased their steps/day by a mean of 408 (4% increase).
	McCarroll 2015 [32]	Logs from the app healthcare provider interface	- Physical activity increased from 77.5185 ± 156.6 Kcal expended and 22.7 ± 44.0 min to 1971.8 ±1105.4 Kcal and 182.3 ± 196.6 min (*P* = .001)[e].
	Oh 2015 [33]	IPAQ-questionnaire [64] MET tracking	- No significant differences.
	Partridge 2015, 2016 [34,35]	IPAQ-SF[g] [65]	- Number of PA days increased more in the intervention group *P* < .01 compared to the control group (*P* = .02).
	Safran 2015 [37]	Questionnaire based on IPAQ[h] [64]	- The mean change in the weekly duration of PA was increased in 63±20.8 minutes in the App group and reduced in 30±-27.5 minutes in the control group (*P* = .02)[e].
	Spook 2015 [38]	Ad-hoc questionnaire	- No differences between intervention and control groups.

	Svetkey 2015 [39]	Paffenbarger questionnaire [66]	- No significative changes in PA performance (kcal/week) in any of the three groups: control, personal coach or cellular phone interventions.
	Aschbrenner 2016 [40]	Cardiorespiratory fitness with the 6-MWT [67]	- Clinically significant improvements in cardiovascular fitness defined as >50 meter increase on the 6-MWT (17%). - Overall change in fitness was not significant.
	Quintiliani 2016 [45]	IPAQ [64]	- Moderate and Vigorous PA increased 545 and 792 respectively, MET[i] minutes per week (ns).
	Garcia-Ortiz 2018 [48]	ActiGraph GT3X accelerometer 7-day PA Record Semi structured interview where	- Decrease of PA in both groups - The intervention subgroup with high App adherence had better behavior than the low adherence subgroup (ss).
	Hurkmans 2018 [52]	Triaxial accelerometer (ActiGraph wGT3X-BT)	- No significant group PA time effects found.
Changes in dietary pattern	Nollen 2014 [27]	24-hour standardized dietary record [68]	- Fruit and vegetable consumption increased (+0.9, *P* = .08). - Sugar-sweetened beverages consumption decreased (-0.3, *P* = .09).
	McCarroll 2015 [32]	Dietary logs from the app healthcare provider interface.	- No significant differences in the macronutrient categories.
	Fukuoka 2015 [30]	Block Food Frequency Questionnaire [61]	- Greater reduction in intake of saturated fat (*P* < .01) in intervention group. - Greater reductions in intake of sugar-sweetened beverages in intervention group (*P* < .01).
	Partridge 2015, 2016 [34,35]	Questionnaires [69,70]	- Fruit and vegetable intake: non-significant difference. - Intervention participants more likely to consume greater quantities of vegetables (*P* < .01). - Sugar-Sweetened Beverage: Intervention participants consumed less (*P* < .01).
	Safran 2015 [37]	The diet quality questionnaire [71]	- App users improved their score significantly at the end of the study from 67±9.8 to 71± 0.6 *P* < .001. No changes seen in control group[e]. - Success score (represents the success in maintaining healthy lifestyle) was higher among the

			App group (68%) compared with 36% in the control group ($P < .001$).
	Svetkey 2015 [39]	Healthy Eating Index [72]	- No significant changes in any of the groups.
	Oh 2015 [33]	Daily meal self-tracking	- No significant changes in any of the groups ($P = 0.12$).
	Spook 2015	Ad-hoc questionnaire	- No differences between intervention and control groups.
	Quintiliani 2016 [45]	PrimeScreen [73] and Beverage Questionnaires (BEVQ-15) [74]	- Daily Fruit and vegetable servings increased (ns). - Diet composition score increased a mean of 6.8 (ss). - Fluid ounces of sugar-sweetened beverages mean increased.
	García-Ortiz 2018 [48]	Mediterranean Diet Adherence Screener [75]	- Both groups (intervention and control) increased adherence to Mediterranean diet with no differences between them.
	Mummah 2017 [50]	Harvard FFQ[j] [76]	- Daily vegetable consumption was significantly greater in the intervention versus control condition: 2.0 servings; $P = .04$ for FFQ.
	Hurkmans 2018 [52]	Digital FFQ [77]	- All groups reduced their total energy intake; only significant changes were found within the 3 intervention groups: conventional group ($P < .01$), App group ($P < .01$), and combined group ($P < .001$) and not in the control group ($P = .22$).
Emotional wellbeing	Pretlow 2015 [36]	Likert scale	- Self-esteem improvement: 2.78±0.19 baseline and 3.59±0.17 program completion ($P < .01$)[e]. - Less likely to turn to food when stressed: 1.93±0.18 baseline and 3.22±0.22 program completion ($P < .01$)[e].
	McCarroll 2015 [32]	Functional Assessment of Cancer-Therapy-General (FACT-G) [78] and Weight Efficacy Life-Style Questionnaire (WEL) [79]	- No statistically significant differences in quality of life measures ($P > .05$).
Screen time	Nollen 2014 [27]	Questionnaire of Television Viewing and Computer Use	- No significant associations were seen between the device utilization and screen time.
Biochemical	Fukuoka 2015 [30]	Non defined	- No differences at 5 months post intervention of blood levels of fasting lipids or glucose between

measure ments			control and intervention group.
	Oh 2015 [33]	Non defined	- No differences between the two groups.
	Block 2015 [28]	Nos defined	- The ratio of TG[k]/HDL[l] reduced in intervention group (mean -0.21, 95% CI[m] -0.30 to -.012); it was increased in the control group (mean 0.21, 95% CI 0.12-0.29) (*P* = .04).
	Willey 2016 [46]	Non defined	- HDL levels increased 4.0 mg/dL (*P* = .04) and trend towards a reduction in total cholesterol of 10.5 mg/dL (*P* = .07) and triglycerides of 27 mg/dL (*P* = .07). - A slight and non-significative reduction of HbA1C[n]; mean values reduced from 5.5 to 5.4%.
	Hurkmans 2018 [52]	CardioChek Point-of-Care Self-Test device Glucose BGStar measurement (Sanofi)	- Within the conventional group, App group, and combined group, a decrease in metabolic risk factors was found, but this change was not significant (*P* = .12, *P* = .15, and *P* = .23). No specific results for glucose or fasting lipids are shown.
Blood pressure	Fukuoka 2015 [30]	Standards protocol	- The intervention group had greater reductions in blood pressure, both SBP[o] and DBP[p] (*P* < .01).
	Willey 2016 [46]	Non defined	- SBP and DBP were significantly lower. Mean SBP and DBP fell 18.6 and 6.4 mmHg (*P* < .01).
	Mao 2017 [51]	Change in SBP	- Mean reduction in SBP after 4 months in the intervention group 6.0±1.6 (*P* < .01)[e].

[a] ss = significant (P value not available)
[b] ns = non-significant (P value not available)
[c] ITT = intention to treat analysis
[d] BMI = body mass index (measured as kg/m^2)
[e] values are expressed as mean±SD
[f] PA = physical activity
[g] IPAQ – SF = International Physical Activity Questionnaires - Short Form
[h] IPAQ = International Physical Activity Questionnaires
[i] MET = metabolic equivalent of task
[j] FFQ = Food Frequency Questionnaire
[k] TG = Triglycerides
[l] HDL = high-density lipoprotein level
[m] CI = Confidence interval
[n] HbA1c = Haemoglobin A1c
[o] SBP = systolic blood pressure
[p] DBP = diastolic blood pressure

Weight and Body Mass Index

Most of the studies (22 out of 28, 78.6%) considered reduction of weight and/or BMI as the main outcome with which to assess intervention efficacy. Devices used to measure weight and/or height were detailed in 17 trials, and only a few relied on self-reported data [35,49,51]. Partridge et al. [35] did not report any differences between self-reported data and scale measures. All trials measured reduction in body weight, but in three studies [39,47,49] there were no differences between control and intervention groups; three other studies [23,37,52] noted differences between groups, but if statistical significance is taken as $P < .05$ these did not reach the threshold. Interventions that included face-to-face elements produced significantly better final outcomes [39,52]. Five other two-arm trials showed a clear and statistically significant reduction in body weight [24,30,35,51]. All pretest-posttest single-arm studies also measured weight reduction after intervention but this was not always significant [41,42,45]; in one of these studies, considered to be of low quality, all weight was fully regained by 24 weeks after the intervention [42].

Fat mass

Fat mass reduction was measured in three studies [23,33,43] through bioelectrical impedance, producing controversial results. In the two RCTs [23,33] fat reduction was statistically significant when comparing control and intervention groups. In a single-arm trial [43] reduction was not statistically significant.

Waist and hip circumferences

Fukuoka et al. [30] measured changes in hip circumference, noting significant changes in the intervention group. Eight trials [28,32,37,41,43,46,49,52] measured changes in waist circumference, although the protocols in use varied or were not clearly specified. Results were controversial. Safran et al. [37] and He et al. [49] reported no changes, whereas five trials [28,32,41,43,46] identified a clear and significant reduction in waist circumference, while Hurkmans et al. [52] recorded non-significant reductions.

Dietary pattern

We identified twelve trials that assessed changes in dietary patterns [27,30,50,52,32–34,37–39,45,48]. All trials employed two-arm pretest-posttest analysis, except for Quinitliani et al. [45] and McCarroll et al. [32]. Only three [32,33,38] did not use validated and previously published tests or questionnaires. Six studies [32–34,38,39,48] found no change when comparing fruit and vegetable consumption or the macronutrient composition of daily

diet between two groups, although the intervention group appeared to adhere more closely to a Mediterranean diet [48] or were more likely to consume vegetables [34]. Other studies were able to demonstrate a clear improvement in dietary patterns: Fukuoka et al. [30] observed a clear decrease in the intake of saturated fat, Mumah et al. [50] identified a higher intake of vegetables, Safran et al. [37] observed an improvement in diet quality, and Hurkmans et al. [52] noted a clear and significant decrease in total energy intake. Both Nollen et al. [27] and Quintiliani et al. [45] perceived a statistically insignificant increase in fruit and vegetable consumption. In regard to sugar-sweetened beverages, two studies were able to measure a significant [30,34] or slight decrease [27]. Unexpectedly, participants in the single-arm study by Quintiliani et al. [45] consumed more sugar-sweetened beverages after the intervention.

Physical activity pattern

Fourteen of the 28 studies (50%) had physical activity pattern as a main end-point. Various strategies were used to measure physical activity: a) Data tracking through accelerometers [29,48,52], pedometers [30], armband sensors [26,29] or logs from the apps [32]; b) Standard questionnaires such as IPAQ or IPAQ-SF [33–35,45], the Paffenbarger Physical Activity Questionnaire [39], or a modification of the IPAQ questionnaire [37]; c) Semi-structured interviews [48]; and d) ad-hoc questionnaires [38]. The most common measurements were daily number of steps [29–31,48,52] and time spent doing physical activity [26,29,32,35,37,40]. The number of MET [33,45] and weekly self-reported spent kcals [39] were also used.

All studies except four [33,38,39,48] showed an improvement in physical activity patterns. However, only five of these stated that the improvement was statistically significant [26,30,32,35,37].

Emotional wellbeing

As the intervention assessed was based on an addiction treatment approach, Pretlow et al [36] analyzed changes in self-esteem and the likelihood of turning to food when feeling stressed. They reported a significant improvement in self-esteem and control of participants' eating. The McCarroll trial [32] analyzed changes in quality of life for cancer survivors. There were no differences before and after the mHealth intervention.

Screen time

Nollen et al. [27] studied possible changes in screen time but recorded no differences between the control and intervention group.

Biochemical measurements

As blood fasting lipids and glucose levels are usually high among people with overweight and obesity, five studies included these as secondary outcomes. Only Block et al. [28] could report a significant improvement in TG/HDL ratio. Two studies [48,52] showed a trend towards reduction but the results were not significant. The other two trials did not measure any change in either fasting lipids or glucose [30,33].

Blood pressure

Fukuoka [30], Willey [46] and Mao [51] tracked changes in blood pressure as a secondary outcome. The three trials were able to measure significant reductions in both SBP and DBP.

Safety

One high quality trial [33] considered safety an outcome to be measured. The aim of this study was to evaluate the effect of SmartCare intervention in patients with metabolic syndrome. They identified a number of mildly adverse events (14.2% in the intervention group and 13.3% in the control group). There were also serious adverse events: 1.4% corresponding to 3 cases in the intervention group, including one ankle fracture; and 2.4% (5 cases) in the control group, including dislocated vertebra, stress urinary incontinence and the need for a knee operation.

Effectiveness

Only one study was targeted at the general population. He et al. [49] conducted a low quality trial on 15.310 people. No differences between the intervention and control group were shown in terms of losing weight.

Discussion

Main results

In conducting this systematic review, we have identified the range of dimensions and tools used to assess the efficacy of mHealth interventions intended to manage overweight and obesity. We have provided a descriptive analysis of 28 clinical trials along with an account of the components and elements included in each intervention. Outputs and outcomes used for the evaluation of trials have also been identified. No specific

criteria for assessing safety or effectiveness have been identified due to the small number of studies focused on these aspects.

Our results show that researchers use the following primary end-points to measure a study's success: a) reduction in weight and/or Body Mass Index (BMI); b) reduction in fat mass; c) reduction in waist and hip circumference; d) improvement in dietary habits/patterns; e) increase in physical activity; f) increase in emotional wellbeing; g) decrease in screen time patterns; h) improvement in biochemical measures; and i) decrease in blood pressure. All these factors are closely linked to obesity and overweight and are risk factors for future chronic disease. Although the main aim of most of the studies was to measure the efficacy of mHealth interventions, they also measure other outputs that might be relevant for determining the success of the intervention, such as a) acceptability b) adherence, usability, engagement c) satisfaction d) motivation e) intention to continue and f) perceived support. All these aspects appear to affect whether an intervention will be successful. Tests and questionnaires are the most prevalent tools used for assessment, whether existing and previously validated or devised for the situation. Objective data tracking of physical activity performance through the mHealth based intervention, when possible, was a common strategy for avoiding self-reported data. It appears to be highly important to gather objective data and use standardized protocols when assessing the usability and efficacy of mHealth interventions. The mHealth strategies considered to be more sophisticated usually include a higher number of elements. Although the recent strategies of peer-support and gamification appear to improve efficacy by increasing engagement and motivation, there is as yet not enough evidence to state this definitively.

Acknowledgement and evaluation of comprehensive socio-demographic differences, such as race/ethnicity, socioeconomic status and sex, is severely lacking. Future analyses of mHealth interventions should consider, and whenever possible, include eHealth literacy aspects in an effort to reduce communication inequalities across groups [80]. Unless designers and developers of healthcare information technologies address security challenges, benefits from healthcare information technology will be scarce [81]. Another aspect we have found to be lacking from m-Health evaluation studies is assessment of clinical data confidentiality.

Previously published reviews have concluded that despite a lack of evidence concerning the best use of technology in weight loss interventions, when the optimal combination of technological components is determined, technology-based interventions will be a valid tool for weight loss [82]. Others have been less optimistic and feel that future studies must use larger study samples, longer interventions, and follow-up periods [83]. One meta-systematic review concluded that despite the increasing popularity of mHealth, evidence for

efficacy is still limited due to the low methodological quality of research [84]. We believe the issue may be how mHealth strategies are assessed and validated: this cannot be carried out in the same manner as research into drugs, and more adapted and/or flexible approaches are needed to explore new evaluation tools. An instrument intended to evaluate m-Health should include verification of its scientific content and mechanisms that ensure data privacy as well as safe usage. Verification of these aspects would ideally be mandatory prior to release and use in clinical practice. In a second phase, evaluations of effectiveness, efficacy, and usability should include user feedback, and adaptability and cost-effectiveness should also be addressed. This second phase of evaluation could be quantitative, enabling assessment of an mHealth intervention's quality and comparison with others.

Currently, most apps used or prescribed in daily clinical practices have only received technical verification or partial clinical validation based on a small group of patients.

Future research is necessary in order to better assess mHealth interventions in development and prior to clinical application. It is important to find a balance between the necessary development of mHealth, which should be characterized as disruptive, innovative and rapid, and the imperative need to validate mHealth interventions. From a Public Health point of view it is necessary to avoid or minimize the potential problems a new mHealth intervention might create without accurate evaluation. It has been argued that the app market regulates itself: the good persist; the bad disappear. However, in such a potentially harmful field as mHealth there is a need for new approaches and tools, and a multi-disciplinary assessment process [14,85–89].

Limitations

One of the main limitations of this review is publication bias. References from other sources such as conferences and meetings have not been included. Although the number of scientific journals that publish mHealth related articles has increased in recent years, there is a lot of grey literature surrounding this field that we may have missed. Moreover, only studies published in English, French or Spanish have been included. The heterogeneity of interventions and populations and the low number of participants in many studies have made it difficult to synthesise results. Most of the studies included were deemed to be of moderate-low quality and consequently findings need to be considered with caution. Eleven of the studies lacked a control group and therefore results cannot be attributable to the technology-based intervention alone. One must also take into account the established fact that individuals who agree to participate in intervention studies have greater motivation to change their lifestyles than the general population.

Finally, only one study was identified with the primary aim of assessing the safety and effectiveness of an mHealth intervention. Given awareness of safety related issues such as a possible increase in anxiety and stress due to the use of mHealth intervention and the possible promotion of eating disorders, this is rather surprising. Furthermore, the studies reviewed largely assessed dietary habits and physical activity, ignoring other possible outcomes relating to body weight such as sleeping behaviour. This also needs to be addressed in future research.

Conclusions

The potential for apps to positively help users manage their obesity or overweight has yet to be attained. Studies assessing the success of mHealth interventions are remarkably heterogeneous and most have methodological limitations that leave significant room for improvement regarding quality. Further research is needed to identify all relevant criteria for assessing the efficacy of mHealth interventions in the prevention and management of overweight and obesity.

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Conflict of Interest

None declared.

Abbreviations

App: mobile application
BMI: body mass index
c: control group
CI: confident interval
CT: controlled trial
DBP: diastolic blood pressure
FFQ = Food Frequency Questionnaire
HbA1c: Hemoglobin A1c

HDL: high-density lipoprotein level
i: intervention group
ITT: intention to treat analysis
IPAQ: International Physical Activity Questionnaires
IPAQ-SF: International Physical Activity Questionnaires - Short Form
MET: metabolic equivalent of task
mHealth: mobile health
No Inf: no information available
ns: non-significant (*P* value not available)
PA: physical activity
PRISMA: referred Reporting Items for Systematic Reviews and Meta-Analysis
RCT: randomized control trial
SB: systolic blood pressure
SIGN: Scottish Intercollegiate Guidelines Network
ss: significant (*P* value not available)
TG: Triglycerides
WHO: World Health Organization

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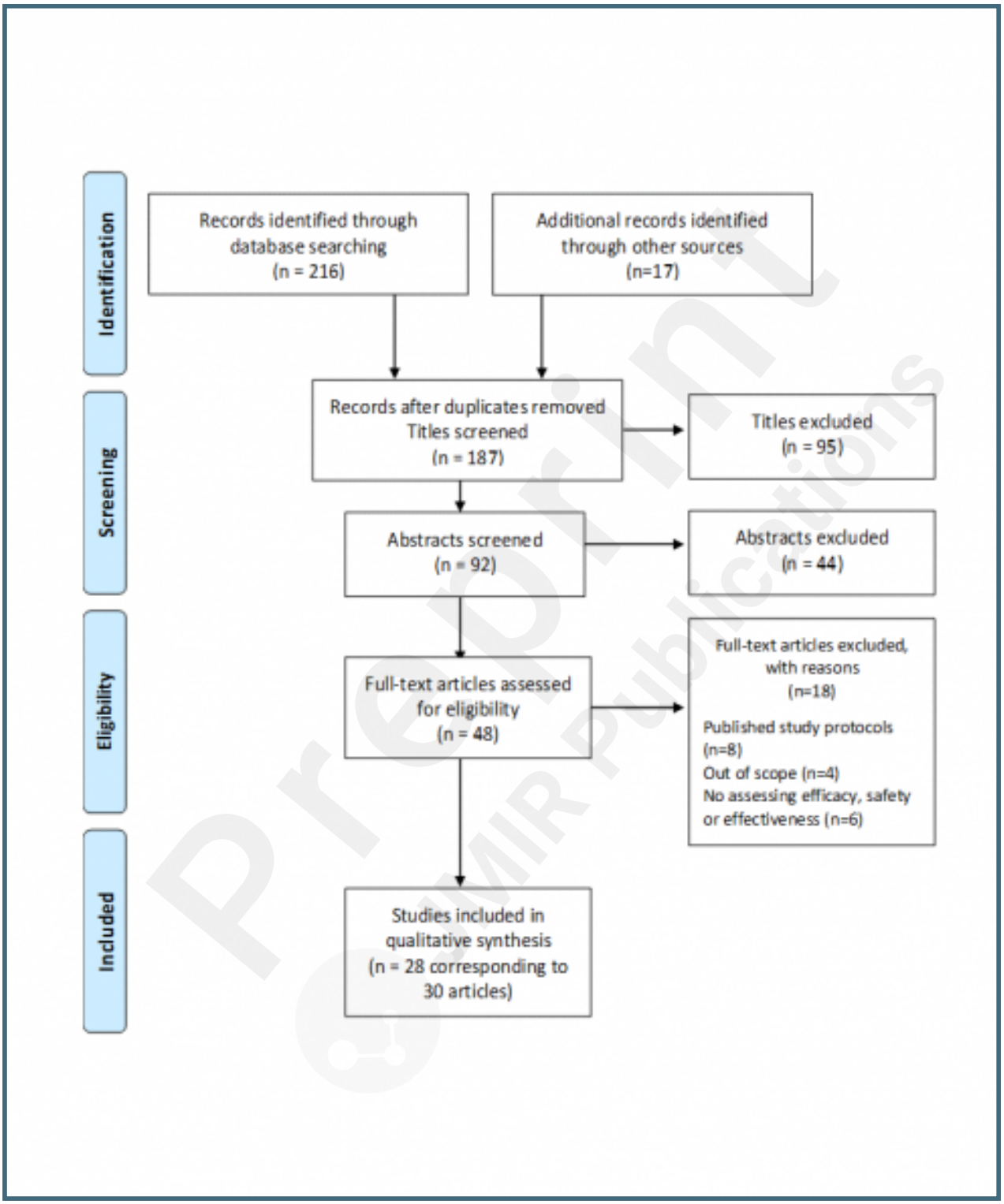
Supplementary Files

Figures

Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram of selection of papers for inclusion in the review.



Multimedia Appendixes

Search strategy.
URL: https://asset.jmir.pub/assets/1c4e0a23509fc41a475ce5c927f26f7f.pdf

Excluded publications.
URL: https://asset.jmir.pub/assets/bc81f5b2f8083c2e381f3d597d93b4b6.pdf