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eHealth interventions for reducing cardiovascular disease risk in men: **aA** systematic review and meta-analysis

 The corrections made in this section will be reviewed and approved by a journal production editor.

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ABSTRACTabstract

Men remain at a higher risk of developing cardiovascular disease (CVD) than women and behavioral risk factor modification is an important preventive measure. However, engaging men in behavior change interventions is challenging. Although men often indicate a preference for gender-specific information and support, this rarely occurs. eHealth interventions have the potential to address this gap, though their effectiveness for reducing CVD risk in men is unclear. Therefore, the aim of this systematic review and meta-analysis was to evaluate the effectiveness of eHealth interventions for reducing CVD risk in men. A search of published randomised controlled trials with no date restrictions up to July 2020 was conducted to identify those targeting at least two major CVD risk factors. Nine trials were identified and reviewed. Study quality ranged from low to unclear, with one trial at a high risk of bias. Compared to those in a control group or receiving printed materials, participants randomised to an eHealth intervention had statistically significant improvements in BMI ($Z=-2.75$, $p=0.01$), body weight ($Z=-3.25$, $p=0.01$), waist circumference ($Z=-2.30$, $p=0.02$) and systolic ($Z=-3.57$, $p=0.01$) and diastolic ($Z=-3.56$, $p=0.01$) blood pressure. Though less evident, there were also improvements in physical activity and diet in favour of the intervention group. This review suggests that eHealth interventions can reduce CVD risk in adult men through behavior change. However, we were unable to determine the association between intervention characteristics and outcomes. Also, overall, participant adherence to the intervention was poor. Both of these issues should be considered in future studies.

Keywords: eHealth interventions; Cardiovascular risk; Men; Systematic review; Meta-analysis

06 **1** Introduction

Cardiovascular disease (CVD) is the leading cause of death and disability, with men at an increased risk compared to women and at an earlier age (Virani et al., 2020). The higher risk can partly be explained by male lifestyle choices, such as poor dietary habits (Vari et al., 2016; White et al., 2011) and a higher consumption of alcohol (Moinuddin and Goel, 2016; White et al., 2011), as well as poor health seeking behaviors compared to females (White et al., 2011; Yousaf et al., 2015). Behavioral risk factor modification of physical inactivity, poor diet, smoking and alcohol consumption is key in the prevention of CVD (Turco et al., 2018; World Health Organization, 2017). However, engaging men in behavior change interventions aimed at reducing CVD is challenging and uptake is low. Although men express a preference for interventions to be targeted specifically at them (Drew et al., 2020; Gavarkovs et al., 2016; Young et al., 2012), this rarely occurs. In a review of 244 weight loss studies, only five were targeted specifically at men (Pagoto et al., 2012). Similarly, in two systematic reviews, one of 58 studies aimed at increasing physical activity (Malik et al., 2014), and the other of 51 studies aimed at reducing sedentary behaviors (Martin et al., 2015), only two studies in each comprised a male only sample.

An additional challenge lies in the recruitment of men to participate in such studies. A scoping review of 25 chronic disease prevention and management studies (Gavarkovs et al., 2016) identified several barriers to engaging men in lifestyle-based interventions, including work commitments, poor health seeking behaviors and perceptions that the interventions were 'inherently feminine'. Men appear to accrue greater benefits from a gender-tailored intervention that

takes into consideration the method of engagement, how the information is presented and its mode of delivery (Duncan et al., 2012; Gavarkovs et al., 2016). To improve engagement, uptake and adherence by men, interventions need to be tailored to males using gender-specific information, offer a preferred mode of delivery and include male only participants (Bottorff et al., 2015; Gavarkovs et al., 2016). eHealth interventions show much potential to meet these needs via easily accessible and individually tailored content (De Vries and Brug, 1999; Muellmann et al., 2016).

Systematic reviews and meta-analyses have demonstrated the positive impact of eHealth interventions on common CVD risk factors, such as promoting physical activity (Davies et al., 2012; Jahangiry et al., 2017; Kroeze et al., 2006; Norman et al., 2007) and healthy dietary behaviors (Kroeze et al., 2006; Norman et al., 2007) among adults, yet there is a dearth of evidence pertaining to male only samples. Exceptions are male-only weight loss programs which may effectively engage and assist men with weight loss (Young et al., 2012) and male-only lifestyle interventions which improve men's mental health in some circumstances (Drew et al., 2020), though the authors of these reviews note that more high quality studies are needed. The aim of this study was to systematically review and meta-analyse published randomised controlled trials to identify the effectiveness of eHealth interventions for reducing CVD risk in men.

2.2 Methods

This review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009) and principles laid out by the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2019). A protocol for this systematic review is located on the PROSPERO international database (identification number: CRD42019137841).

2.1.2.1 Search strategy

We conducted a search of published randomised controlled trials (RCTs) of eHealth interventions for reducing CVD risk in men through the Cochrane Central register of Controlled Trials (CENTRAL), Medline, CINAHL Plus, PsycINFO and SCOPUS databases, initially in May 2019 then updated in July 2020; no restriction was placed on year of publication. Reference lists of relevant systematic reviews and meta-analyses were searched manually for additional trials not found during the search. Articles published only as an abstract or a conference presentation or in a language other than English were excluded.

2.2.2.2 Study eligibility

Eligible studies were RCTs that used eHealth interventions targeting a minimum of two major CVD-related risk factors (e.g. weight, physical activity, diet) in males aged over 17 years. eHealth is defined as the use of technology (in this instance mobile phones, computers, laptops, tablets) to improve health, wellbeing and healthcare (van Gemert-Pijnen et al., 2018).

2.3.2.3 Study selection process

All studies identified through the search strategy were imported into Covidence, a software platform that streamlines the production of systematic reviews. Once duplicates were removed, remaining titles and abstracts were screened independently by three reviewers (JM, DRT and KB). Remaining studies then underwent full text review by two reviewers (JM and KB). Any disagreements during screening and full text review were resolved through a fourth reviewer (CFS).

2.4.2.4 Data extraction

Data extraction was conducted independently by two reviewers (JM and KB) using a predesigned data extraction form. Any disagreements were then discussed and settled by a third reviewer (CFS). The following data were extracted: country undertaken, aims, setting, participant and intervention characteristics, study methodology, and outcomes. Means (*M*), standard deviations (*SD*) and sample sizes (*n*) were also extracted.

2.5.2.5 Data analysis and synthesis

Meta-analysis was undertaken using Comprehensive Meta-Analysis Version 3 (CMA Version-3) software. The analysis compared the effect of the intervention with the control or comparison group on body mass index (kg/m^2), body weight (kg), waist circumference (cm), systolic blood pressure (mmHg) and diastolic blood pressure (mmHg). A funnel plot was used to examine publication bias. Sensitivity analyses were performed using 'one-study-removed' method; results of this are only presented in text when removal of a study affected the outcome. A random-effects model was used in all analyses, weighting the studies based on the sample size/standard error. In cases when pre-post correlations were not reported in the published papers, we used a 0.5 correlation.

For the meta-analysis we report the mean difference. Hedges' *G* (*g*) form of the SMD was used. Results using completers only were used when intention-to-treat (ITT) results were not reported. We report the confidence interval

(CI), the Z-value, *p*-value and *I*² statistic (Borenstein et al., 2009). For those outcomes not included in the meta-analysis, we provide a narrative synthesis.

2.6.2.6 Quality assessment

The quality of the included trials was assessed using the Cochrane risk of bias tool (Version 1) (Higgins et al., 2011) concurrently by two reviewers (JM and KB). The following sources of bias were assessed: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessor, incomplete outcome data and selective outcome reporting. Risk of bias across all domains was assessed using the classifications recommended by Cochrane (Higgins et al., 2019) (Table 1). A summary risk of bias for each study was also created using these criteria. Heterogeneity between studies was assessed using *I*² in the quality assessment.

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Risk of bias classification criteria (Higgins et al., 2019)

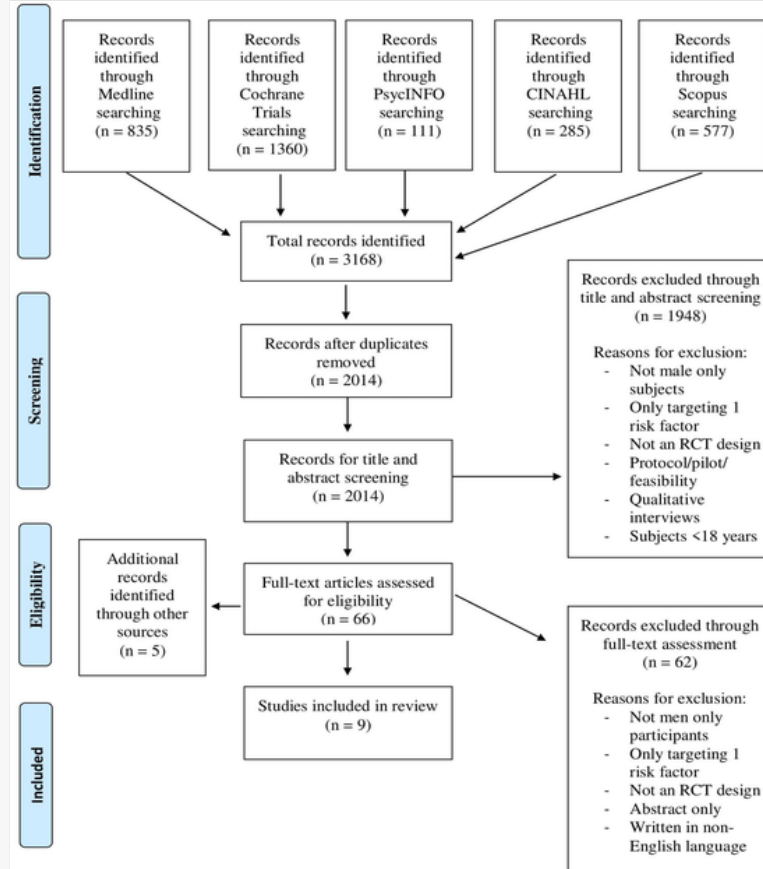
- Low risk of bias: All domains judged to be at a low risk of bias
- Some concern (unclear): Judged to raise some concerns (unclear) in at least one domain
- High risk of bias: A minimum of one domain judged to be at a high risk of bias
<i>Or</i>
- Multiple domains judged to be unclear and therefore lowering the confidence in the study

3.3 Results

3.1.3.1 Study selection

A total of 3168 records were retrieved through the database searches with 2014 titles and abstracts screened for eligibility once duplicates were removed. Articles that appeared appropriate for this review following title and abstract screening (*n*=66) were assessed via full text screening for their eligibility. Nine trials were assessed as eligible for inclusion in this review. A PRISMA flow-diagram shows the process of study selection and reasons for inclusion/exclusion (Fig. 1).

alt-text: Fig. 1
~~Figure 1~~ Figure 1



PRISMA flow diagram

3-2-3.2 Study characteristics

Of the nine trials reviewed (Table 2), five were conducted in Australia (Duncan et al., 2012; George, 2013; Morgan et al., 2009, 2011, 2013), three in the USA (Crane et al., 2015; Patrick et al., 2011; Veverka et al., 2003) and one in Japan (Tanaka et al., 2010). Six trials targeted men who were overweight or obese (Crane et al., 2015; Morgan et al., 2009; 2011; 2013; Patrick et al., 2011; Tanaka et al., 2010), two middle aged (Duncan et al., 2014; George, 2013) and one in the military (Veverka et al., 2003). One trial was a PhD thesis (George, 2013).

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Table 2: Table 2

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Characteristics of included studies

Author, Year, country	Study design, participants, sample size, age	Intervention	CVD-related outcomes	Data collection time points
Crane et al., 2015 USA	RCT, overweight or obese	Theory use: y Yes, social cognitive theory and self-determination theory Duration: 6 months	Body weight, BMI, waist circumference, diet, physical activity	Baseline, 3, 6 months

	men, n = 107, mean age = 44.2 years	Intended dose: W Weekly IG: T Two 1- hour face-to-face group sessions for recommendations on diet, physical activity, self-monitoring behaviors; future contact delivered on-line; self-evaluation of behaviors for personalised recommendations; automated tailored feedback; SMART goals set each week; modest calorie deficit, minimum of 6 separate 100- calorie changes; weekly online lesson on dietary strategies; progressive exercise plan with target of 225- minutes ; min exercise per week CG: W Waitlist; no recommendations		
Duncan et al., 2014 Australia	Two-armed RCT, middle-aged men, n = 301 mean age = 44 years	Theory use: Y Yes, social cognitive theory and self-regulation theory Duration: 9 months Intended dose: N Not stated IG: W Website and mobile phone platform; materials on physical activity, dietary behaviors, self-monitoring of behaviors; goal setting; progress tracking; automated feedback on progress; social support; M Man- U p' challenges (6 on physical activity, 1 on healthy eating) CG: P Print-based materials covering the same topics provided to IG; self-monitoring of behaviors	Physical activity, dietary behaviors	Baseline, 3, 9 months
George et al., 2013 Australia	Two-armed RCT, middle-aged men employed at a university, n = 56, mean age = 48.2 years	Theory use: N No, social ecological approach to health promotion Duration: 3 months Intended dose: N Not stated IG: adapted from initial Man-Up study (Duncan et al., 2012); 'Man-Up challenges'; goal setting, progress tracking; 'Information centre' for health advice; social forum; email reminders (3, 6, 9 weeks) to access intervention; printed materials on physical activity, sedentary time, health CG: P Print-based comparison group, included materials used in online intervention	Physical activity, sedentary time, body weight, BMI, waist circumference, blood pressure	Baseline, 3, 6 months
Morgan et al., 2009 Australia	RCT, overweight or obese men, n = 65, mean age = 35.9 years	Theory use: Y Yes, social cognitive theory Duration: 3 months Intended dose: 7 individualised feedback sheets IG: I Initial face-to-face session covering diet, physical activity, behavior change strategies (self-monitoring, goal setting, social support); online website (CalorieKing) with information, tools to improve diet, physical activity; progress tracking; weekly diaries for first 4 weeks, 2 weeks in second month, 1 week in third month for individualised feedback, encouragement, reinforcement; 'notice board' for questions to research team CG: I Initial information session, print-based resources relating to online intervention	Body weight, BMI, waist circumference, blood pressure, physical activity, dietary behaviors,	Baseline, 3, 6 months
Morgan et al., 2011 Australia	Two-armed RCT, overweight or obese men, n = 110, mean age = 44.1 years	Theory use: Y Yes, social cognitive theory Duration: 3 months Intended dose: 7 individualised feedback sheets IG: modelled on SHED-IT program (Morgan et al., 2009): initial face-to-face education session on energy balance, challenges of shift work related to diet, exercise, weight loss tips for men, behavior change strategies; online website (CalorieKing); submit weight weekly; daily eating and exercise diary each week for first month, twice in second month, once in third month for individualised feedback, personalised weight loss strategies; self-monitoring, skills for better weight loss behaviors, goal setting; weight loss handbook and pedometer CG: W Waitlist	Body weight, waist circumference, BMI, blood pressure, resting heart rate, physical activity, dietary habits	Baseline, 14-weeks
Morgan et al., 2013 Australia	Three-armed RCT, O Overweight or obese men, n = 159, M Mean age = 47.5 years	Theory use: Y Yes, social cognitive theory Duration: 3 months Intended dose: 7 individualised feedback sheets IG (print-based resources): C Community trial of SHED-IT program; weight loss resource package targeted at men (DVD, handbook, pedometer); physical activity, dietary behavior change, improve key dietary behaviors using "masculinized" tips and strategies, weight loss tips, three SMART goals per month IG (online + print-based resources): S Same materials as print-based intervention group; online website (CalorieKing), input food and exercise diary 4 days per week; goal setting, progress tracking, individualised feedback via email (7 in total) based on	Body weight, waist circumference, BMI, body fat percentage, blood pressure, resting heart rate, physical activity, sedentary time, dietary habits	Baseline, 3, 6 months

		diary entries; strategies for improving diet and exercise behaviors CG: W aitlist		
Patrick et al., 2011 USA	RCT, overweight or obese men, n = 441, mean age = 43.9 years	Theory use: Y es, social cognitive theory Duration: 12 months Intended dose: W eekly IG: W eight loss through diet, physical activity; goal setting, behavioral skills, social support; improving fruit and vegetable intake, reducing saturated fat, increasing whole grain products; 10,000 steps 5 times per week, strength training 2 times per week; computerised assessment for personalised recommendations; weekly web-based activities; pedometers; frequent reassessment for further personalised advice CG: W aitlist, alternate website for general health information	Body weight, BMI, waist circumference, diet, physical activity	Baseline, 6, 12 months
Tanaka et al., 2010 Japan	RCT, overweight men, n = 51, mean age = 46 years	Theory use: N ot stated Duration: 1 month Intended dose: N ot stated IG: E ducational booklet on behavioral weight control, diet, physical activity, self-monitoring with examples; questionnaire for food, physical activity habits, input to "KT" computer system for personalised advice, behavioral techniques, encouragement, skills for change, goal setting, self-monitoring advice; second questionnaire after one month for further advice; understanding barriers, reinforcement, social support CG: R eceived same booklet as IG	Body weight, BMI, blood pressure, blood cholesterol (Total, LDL, HDL, triglycerides), glucose, HbA1c, physical activity, dietary behaviors	Baseline, 1, 3, 7 months
Veverka et al., 2003 USA	RCT, men on active military duty, n = 39, mean age = not stated	Theory use: Y es, transtheoretical model of behavior change Duration: 6 months Intended dose: M inimum once per month IG: O nline survey for participants to be staged, received information on both exercise and diet CG: C ontrol, no intervention or materials	Cardiorespiratory fitness (VO ₂ max), body weight, body fat percentage, BMI, waist-hip-ratio), blood cholesterol (Total, LDL, HDL, triglycerides), blood pressure, resting heart rate	Baseline, 6 months

IG: intervention group; CG: control group

The main CVD-related outcomes assessed were weight (Crane et al., 2015; George, 2013; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011; Tanaka et al., 2010; Veverka et al., 2003), physical activity (Crane et al., 2015; Duncan et al., 2014; George, 2013; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011; Tanaka et al., 2010), diet/nutrition (Crane et al., 2015; Duncan et al., 2014; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011; Tanaka et al., 2010) and related biomarkers/clinical measures: blood pressure, cholesterol, glucose, HbA1c, resting heart rate and cardiorespiratory fitness (VO₂ Max) (George, 2013; Morgan et al., 2009, 2011, 2013; Tanaka et al., 2010; Veverka et al., 2003). Outcomes were reported as mean change scores in five studies (George, 2013; Morgan et al., 2009, 2011, 2013; Tanaka et al., 2010), pre-post means and SD or CI within each group in three studies (Crane et al., 2015; Patrick et al., 2011; Veverka et al., 2003) and as exponentiated coefficients in one study (Duncan et al., 2012).

Of the nine trials, three incorporated an initial face-to-face session prior to engaging in the online component of the intervention to provide behavioral recommendations (Crane et al., 2015; Morgan et al., 2009, 2011). Most trials provided tailored feedback on behavioral habits (Crane et al., 2015; Duncan et al., 2014; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011; Tanaka et al., 2010). To increase the success of the intervention in achieving behavior change, educating participants on goal setting (Crane et al., 2015; Duncan et al., 2014; George et al., 2013; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011; Tanaka et al., 2010), self-monitoring/tracking progress (Crane et al., 2015; Duncan et al., 2014; George et al., 2013;

Morgan et al., 2009, 2011, 2013; Tanaka et al., 2010) and social interaction/support (Duncan et al., 2014; George et al., 2013; Morgan et al., 2009; Patrick et al., 2011; Tanaka et al., 2010) was included. In addition to the online component of the intervention, participants in four trials (George et al., 2013; Morgan et al., 2011, 2013; Tanaka et al., 2010) were provided with supplementary resources (i.e. handbooks, DVD, printed materials). One trial (Veverka et al., 2003) provided little to no information on the characteristics of their intervention.

Of the interventions reported in the nine trials, seven were underpinned by theory, two of which used two theories. Six interventions were underpinned by social cognitive theory (Crane et al., 2015; Duncan et al., 2014; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011), one in combination with self-determination theory (Crane et al., 2015) and one with self-regulation (Duncan et al., 2014) - and one by the transtheoretical model of behavior change (Veverka et

al., 2003). One trial (George, 2013) took an ecological approach to health promotion rather than targeting a single theoretical framework, and one did not state whether the intervention was driven by theory (Tanaka et al., 2010).

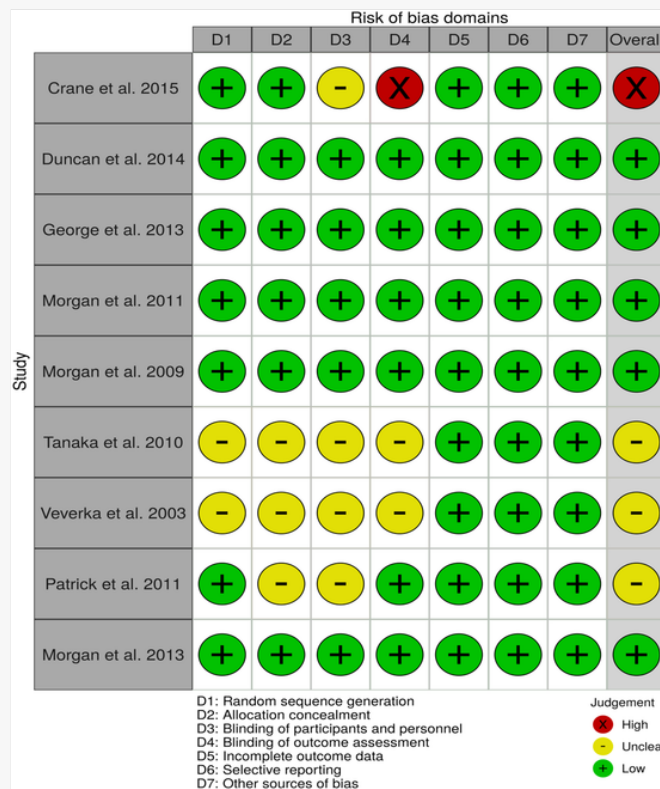
The choice of comparison groups in the nine trials varied: four used a wait-list control group (Crane et al., 2015; Morgan et al., 2011, 2013; Patrick et al., 2011), four used a comparison group which received printed resources related to the online intervention, (Duncan et al., 2014; George, 2013; Morgan et al., 2009; Tanaka et al., 2010) and one used a 'true control' group, i.e. receiving no intervention or materials (Veverka et al., 2003). Mean participant age across the nine trials was 44.2 ± 3.8 years with one trial (Veverka et al., 2003) not reporting age. Study sample sizes ranged from 39- to 441 at the point of randomisation. Intervention durations ranged between one and 12-months with participant retention rates at the final assessment point ranging between 49.2% and 93% with an average of $79.3\% \pm 13.6\%$. Table 2 shows a summary of the study characteristics.

3.3.3.3 Quality of studies

Overall, risk of bias across the included trials was rated as low (Duncan et al., 2014; George, 2013; Morgan et al., 2009, 2011, 2013). Three trials had an unclear risk of bias (Patrick et al., 2011; Tanaka et al., 2010; Veverka et al., 2003), and one a high risk of bias (Crane et al., 2015). Fig. 2 shows a summary of the risk of bias assessment.

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Figure 2, Fig. 2



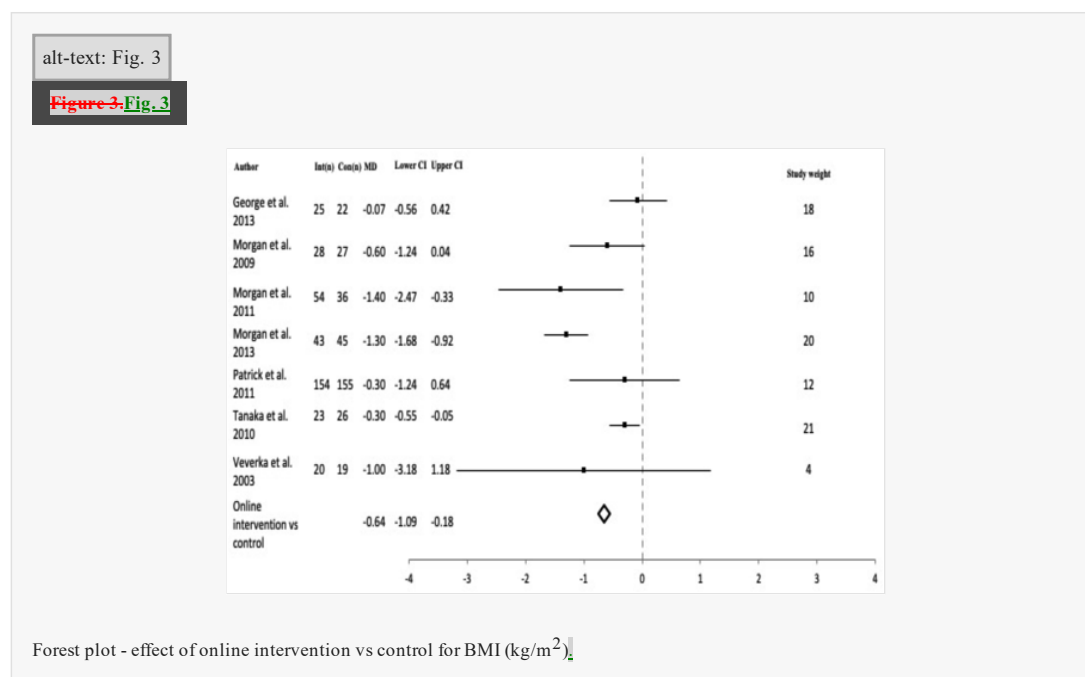
In most trials (Crane et al., 2015; Duncan et al., 2014; George, 2013; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011) the process of randomisation to intervention and control groups was described, thus presenting a low risk of bias (random sequence generation). Allocation concealment to groups was reported in six trials (Crane et al., 2015; Duncan et al., 2014; George, 2013; Morgan et al., 2009, 2011, 2013), but was unclear in three (Patrick et al., 2011; Tanaka et al., 2010; Veverka et al., 2003). The blinding of participants and personnel was unclear in four trials (Crane et al., 2015; Patrick et al., 2011; Tanaka et al., 2010; Veverka et al., 2003). The blinding of outcome assessment varied among trials: the outcome assessor was blinded throughout (low risk of bias) in four (Duncan et al., 2014; George, 2013; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011), two lacked sufficient detail (unclear) (Tanaka et al., 2010; Veverka et al., 2003), and one (Crane et al., 2015) was rated as having a high risk of bias due to non-blinding of the outcome assessor. Risk of bias for both the incomplete outcome data and selective reporting domains was rated as low for all trials.

As identified by the meta-analyses, considerable heterogeneity was present for BMI, body weight and waist circumference (see below), therefore the findings for these should be interpreted with caution. The heterogeneity observed appears to be as a result of study sample sizes as measurement tools were the same for each outcome across trials. No concern about heterogeneity was observed for either systolic or diastolic blood pressure.

3.4.3.4 Meta-analysis

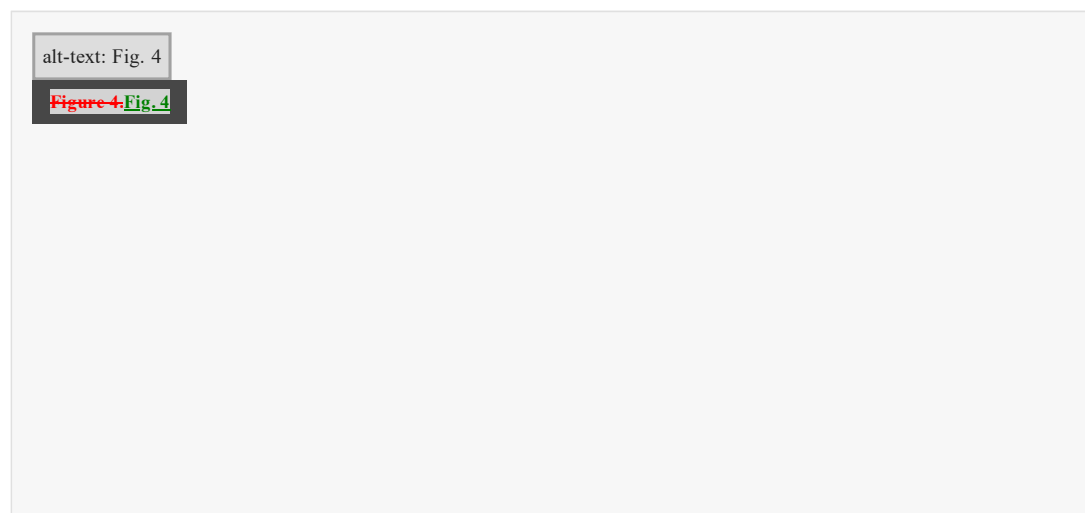
3.4.1.3.4.1 Body mass index

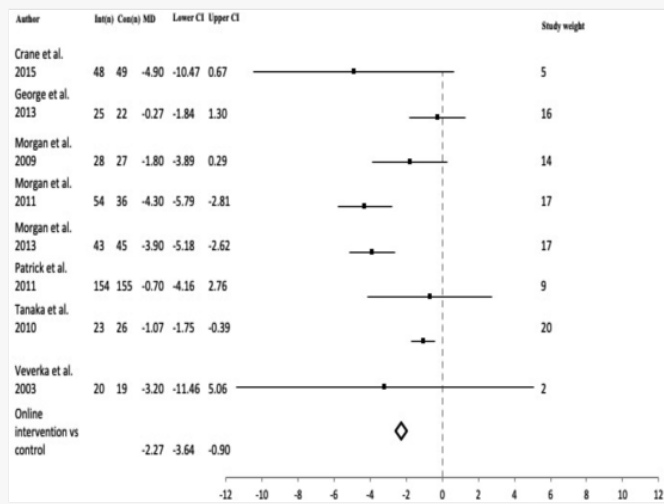
BMI (Fig. 3), measured at post-intervention in seven trials, was reduced by 0.64 kg/m² in the online intervention group compared to a control or resource-based comparison group, $Z=-2.75$, $p=0.01$, $I^2=76.39$. One trial removed from the analysis did not significantly change the study outcome.



3.4.2.3.4.2 Body weight

Body weight (Fig. 4), measured at post-intervention in eight trials, was reduced by 2.27 kg in the online intervention group compared to a control or resource-based comparison group, $Z=-3.25$, $p<0.01$, $I^2=77.34$. One study removed from the analysis did not significantly change the study outcome.





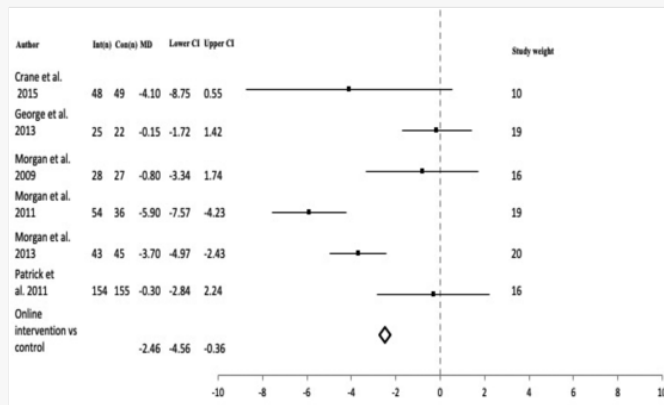
Forest plot – effect of online intervention vs control for body weight (kg)

3.4.3.3.4.3 Waist circumference

Waist circumference (Fig. 5), measured at post-intervention in six trials, was reduced by 2.46 cm in the online intervention group compared to a control or resource-based comparison group, $Z = -2.30$, $p = 0.02$, $I^2 = 84.64$. Removal of the studies by Morgan et al. (2011, 2013) resulted in p -values of 0.09 and 0.12, respectively.

alt-text: Fig. 5

Figure 5. Fig. 5



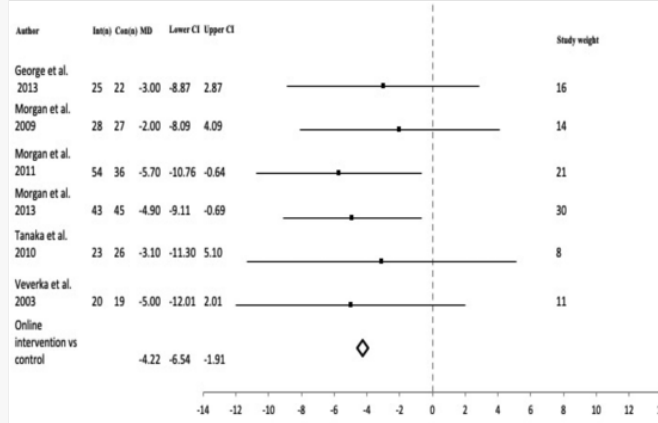
Forest plot – effect of online intervention vs control for waist circumference (cm)

3.4.4.3.4.4 Systolic blood pressure

Systolic blood pressure (Fig. 6), measured at post-intervention in six trials, was reduced by 4.22 mmHg in the online intervention group compared to a control or resource-based comparison group, $Z = -3.57$, $p < 0.01$, $I^2 = 0$. One study removed from the analysis did not significantly change the study outcome.

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Figure 6. Fig. 6



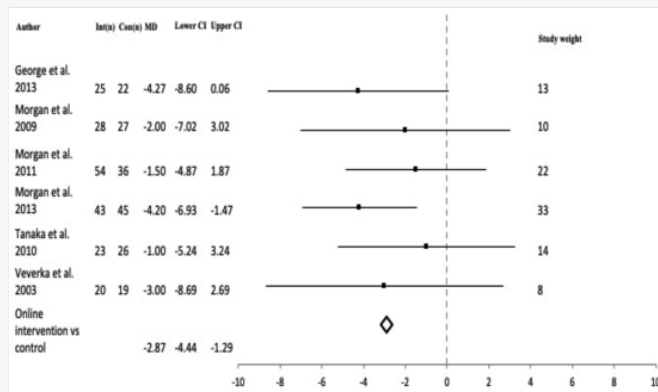
Forest plot – effect of online intervention vs control for systolic blood pressure (mmHg)

3.4.5.3.4.5 Diastolic blood pressure

Diastolic blood pressure (Fig. 7), measured at post-intervention in six trials, was reduced by 2.87 mmHg in the online intervention group compared to a control or resource-based comparison group, $Z = -3.56$, $p < 0.01$, $I^2 = 0$. One study removed from the analysis did not significantly change the study outcome.

alt-text: Fig. 7

Figure 7, Fig. 7



Forest plot – effect of online intervention vs control for diastolic blood pressure (mmHg)

3.5.3.5 Narrative synthesis

3.5.1.3.5.1 Behavioral risk factors

3.5.1.1.3.5.1.1 Physical activity and sedentary time

Physical activity was assessed in eight of the nine trials (Crane et al., 2015; Duncan et al., 2014; George, 2013; Morgan et al., 2009, 2011, 2013; Patrick et al., 2011; Tanaka et al., 2010). Six trials reported improvements in physical activity related outcomes in favour of those in the online intervention group, four of which were statistically significant. Two trials reported time spent sedentary: one measured sedentary time objectively, reporting no change in either group across time-points; the other trial measured sedentary time subjectively, reported non-significant improvements.

3.5.1.2.3.5.1.2 Diet

Diet was assessed by self-report in seven of the nine trials. Measurement tools varied across trials with the most common tools used being the food frequency questionnaire ($n = 3$). Dietary outcomes included: calorie intake (Crane et al., 2015; Morgan et al., 2009, 2013), consumption of bread (Duncan et al., 2014; Morgan et al., 2011), milk (Duncan et al., 2014; Morgan et al., 2011), beverages (Morgan et al., 2011) and alcohol (Morgan et al., 2013). Fruit and vegetable intake were assessed in two trials (Morgan et al., 2011; Patrick et al., 2011) with the percentage of energy from dietary fats and saturated fats assessed in one trial (Patrick et al., 2011). One trial (Tanaka et al., 2010) reported on the intake of processed and fat rich foods, as well as dietary behaviors exhibited by participants. Lastly, portion size was assessed in one trial (Morgan et al., 2013). Five trials reported improvements for dietary outcomes with significant differences between groups observed in one study only.

3.6.3.6 Biomarkers/clinical measures

3.6.1-3.6.1 Resting heart rate

Four trials assessed change in resting heart rate (Morgan et al., 2009, 2011, 2013; Veverka et al., 2003) with improvements observed across all studies post-intervention compared to baseline. Two reported significant improvements in resting heart rate from baseline in the online intervention group with one (Morgan et al., 2011) reporting a significant difference between the online intervention and control group (mean difference between groups = 7.9 bpm).

3.6.2-3.6.2 Blood lipids, glucose and HbA1c

Two trials (Tanaka et al., 2010; Veverka et al., 2003) measured blood lipids and reported improvements in total, HDL and LDL cholesterol for the intervention and control groups and triglycerides in both intervention groups, with the control groups observing increases in triglycerides during the study period. One trial (Veverka et al., 2003) reported greater improvements in all cholesterol measurements in favour of the intervention group. However, the other trial (Tanaka et al., 2010) reported that improvements in total and HDL cholesterol were only greater than the control group at the 1-month assessment, with the control group observing greater reductions than the intervention group at the 3-month assessment point.

Only one trial measured blood glucose and HbA1c levels (Tanaka et al., 2010). Although both the intervention and control groups observed reductions in blood glucose, the online intervention group had greater reductions than the control. HbA1c was reduced at both time points for the intervention group whereas the control group only observed improvements during the 3-month assessment point. There were no significant differences observed between groups for either blood cholesterol, blood glucose or HbA1c.

3.6.3-3.6.3 Cardiorespiratory fitness

One trial assessed change in cardiorespiratory fitness through Vo2 Max testing (Veverka et al., 2003). Although Vo2 Max scores improved in both groups and more in the intervention group, there was no significant difference between the two groups.

4.4 Discussion

To our knowledge, this is the first systematic review and meta-analysis of RCTs of eHealth interventions for reducing CVD risk factors in men. The review found improvements in body weight, BMI, waist circumference and blood pressure among men receiving eHealth interventions compared to a control or printed resources comparison group. Less evident were improvements in physical activity and diet. Although many of these improvements were at a statistical level of significance their clinical significance is likely to be modest.

Our findings compare favourably with reviews of eHealth interventions for CVD prevention that are not for men only - for example, Widmer et al. (2015) found significant reductions in weight and BMI but not blood pressure or other CVD risk factors – as well as for overweight/obese adults (Hutchesson et al., 2015; Lau et al., 2020), physical activity and diet (Kroeze et al., 2006; Norman et al., 2007), or physical activity alone (Davies et al., 2012; Jahangiry et al., 2017).

Even though eHealth interventions are assuming increasing prominence and appeal, they often suffer from poor rates of engagement, uptake and adherence (Kelders et al., 2012). Regarding participant retention, five of the nine trials reported rates exceeding 80%, three exceeding 90% at follow-up, indicating acceptability of eHealth interventions among men. Also, a wait-list control group is a potential mechanism to increase the acceptability of being randomised to a control group and improve retention rates (Darker et al., 2009). This is supported by our review, with the highest attrition rates observed in three of the four trials that used an 'active control': a comparison group provided with printed resources (Duncan et al., 2014; George, 2013; Morgan et al., 2013).

The review found poor adherence rates with the online intervention, with only one trial (Crane et al., 2015) reporting positive rates, with a mean of 90% during the first 12-weeks, declining to 77% from 12 to 22-weeks.

Trials utilising an 'active control' found greater rates of attrition and fewer mean differences between groups for CVD-related outcomes than those utilising a 'true control'. Using an 'active control' has the potential to negatively impact the perceived benefits brought about by the online intervention by minimizing the differences between groups compared to using a 'true control' (Möller, 2011). As indicated in our review, it would be advisable to approach the mean differences between groups in these trials with caution as the true effect of the online intervention may not be as evident.

Seven trials reported the use of a theory-based intervention to enhance behavior change. The application of behavior change theories is strongly advocated by Medical Research Council guidance on developing and evaluating complex interventions (Craig et al., 2008). Previous reviews of eHealth behavior change interventions found that those driven by a theoretical basis were more effective than those that were not (Muellmann et al., 2016; Webb et al., 2010). It is difficult to ascertain the influence of behavior change theories on outcomes in this review, and we can merely speculate,

though the trial (George, 2013) which utilised an ecological approach to health promotion rather than a specific behavior change theory produced the least difference in change between groups for all weight-related outcomes.

Finally, it is important to note that earlier, non-eHealth, reviews of counselling or education interventions (usually face-to-face or group) for primary prevention of CVD have found, at best, only modest declines in risk factors (Ebrahim et al., 2011; Alageel et al., 2017), and we reiterate the plea made by the authors of these reviews for better reporting of the rationale, content and delivery of interventions in order to understand their effectiveness. For example, none of the trials in our review examined the association between intervention characteristics and outcomes, an issue that should be explored in future trials.

4.1.4.1 Limitations

There are a number of limitations to this review. First, due to a lack of translation resources it is possible that relevant studies in a language other than English may have been missed, and more comprehensive reviews addressing this gap are warranted. Second, although improvements were observed for body weight, BMI and waist circumference in statistically significant terms, there was considerable heterogeneity between studies. Third, and related to the second, is the challenge in determining whether such improvements are clinically significant. Fourth, three of the trials were from the same group and overlapped, thus potentially skewing the findings. Fifth, three trials were assessed as having an unclear risk of bias, which points to the need for studies to report clearly and unambiguously issues such as group allocation and blinding. Sixth, we were unable to determine the association between intervention characteristics and outcomes, an issue warranting further exploration.

5.5 Conclusion

The findings of this review highlight the potential effectiveness of eHealth interventions for reducing a range CVD risk factors in men. However, male participant adherence is an issue that warrants being addressed in future studies. Importantly, researchers should also ensure that eHealth interventions are developed with a theoretical underpinning to help understand their effectiveness in this population.

Declaration of Competing Interest

None.

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Appendix A: Appendix A Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.yjmed.2020.106402>.

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i The corrections made in this section will be reviewed and approved by a journal production editor. The newly added/removed references and its citations will be reordered and rearranged by the production team.

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Highlights

- Engaging men in behavior change interventions is challenging
 - Improvements in body weight, BMI, waist circumference and blood pressure were found in men receiving eHealth interventions
 - eHealth interventions targeting men can reduce CVD risk through behavior change
 - Future studies should examine the association between intervention characteristics and outcomes, and adherence in men
-

~~Appendix A~~ Appendix A Supplementary data

[Multimedia Component 1](#)

Supplementary material

alt-text: Image 1

Queries and Answers

Q1

Query: Citation "Tanaka et al., 2013" has not been found in the reference list. Please supply full details for this reference.

Answer: Thank you. We have corrected this to 2010 in Table 2

Q2

Query: Your article is registered as a regular item and is being processed for inclusion in a regular issue of the journal. If this is NOT correct and your article belongs to a Special Issue/Collection please contact m.vs@elsevier.com immediately prior to returning your corrections.

Answer: Yes, this is correct. It is NOT for a special issue

Q3

Query: Please confirm that given names and surnames have been identified correctly and are presented in the desired order, and please carefully verify the spelling of all authors' names.

Answer: These are all correct

Q4

Query: The author names have been tagged as given names and surnames (surnames are highlighted in teal color). Please confirm if they have been identified correctly.

Answer: These are correct

Q5

Query: Please check the address for the corresponding author that has been added here, and confirm if correct.

Answer: This is correct

Q6

Query: Please check the hierarchy of the section headings and confirm if correct.

Answer: This is correct

Q7

Query: Citation "George et al., 2013" has not been found in the reference list. Please supply full details for this reference.

Answer: Thank you. We have deleted et al. It should read George, 2013

Q8

Query: Have we correctly interpreted the following funding source(s) and country names you cited in your article: "Department for the Economy".

Answer: We have added in Northern Ireland, UK. There is no grant ID