A Systematic Review Examining the Effects of mHealth Interventions on Dietary Adherence in Patients with Cardiovascular Diseases

by

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A thesis submitted to the
School of Graduate and Postdoctoral Studies in partial
fulfillment of the requirements for the degree of

Master of Health Sciences (MHSc) in Community, Public and Population Health

Faculty of Health Sciences

University of Ontario Institute of Technology (Ontario Tech University)

Oshawa, Ontario, Canada

April 2022

Thesis Examination Information

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Master of Health Sciences in **Community, Public and Population Health**

Thesis title: A Systematic Review Examining the Effects of mHealth Interventions on Dietary Adherence in Patients with Cardiovascular Diseases

An oral defense of this thesis took place on April 5, 2022, in front of the following examining committee:

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The above committee determined that the thesis is acceptable in form and content and that a satisfactory knowledge of the field covered by the thesis was demonstrated by the candidate during an oral examination. A signed copy of the Certificate of Approval is available from the School of Graduate and Postdoctoral Studies.

Abstract

A systematic review was conducted to determine if diet-focused mHealth interventions are effective for supporting dietary adherence in patients with cardiovascular disease (CVD), a population where nonadherence is common. A comprehensive literature search identified thirteen studies which met inclusion criteria: adults with a CVD diagnosis, use of an mHealth intervention, and measures of dietary adherence. Studies were excluded if interventions involved open dialogue or were qualitative studies or systematic reviews. Eight studies supported using mHealth interventions for improving dietary adherence, four showed mixed results, and one showed no improvements. Eight studies evaluated text and/or app-based mHealth interventions and found that their interactive features improved dietary adherence more compared to solely information delivering interventions. Overall, most mHealth interventions improved dietary adherence, however, nine studies had high risk of bias due to the outcome measurement, thus caution is advised when applying these findings to clinical settings for patients with CVD.

Keywords: mHealth; dietary adherence; hypertension; coronary artery disease; heart failure

Author's Declaration

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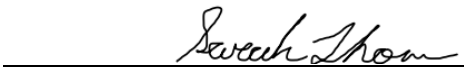

Sarah Thom

Statement of Contributions

I was responsible for writing each section of this thesis, data extraction, and the narrative synthesis of the data. The study was designed by myself and my thesis supervisor, Dr. JoAnne Arcand. The search strategy detailed in Appendix A was synthesized with the assistance of a medical librarian. My colleagues were second reviewers for the literature search and the risk of bias assessments detailed in Appendix B.

I hereby certify that I am the primary author of this thesis and that no part of this thesis has been published or submitted for publication. I have used standard referencing practices to acknowledge ideas, research techniques, or other materials that belong to others. Furthermore, I hereby certify that I am the sole source of the creative works and/or inventive knowledge described in this thesis.

Acknowledgements

I would first and foremost like to thank Dr. JoAnne Arcand without whom none of this would be possible. She has been extremely supportive, patient, and kind throughout the entire thesis writing process and I would not have learned near as much as I did at Ontario Tech without her. Also, thank you to Maria Tan, the medical librarian who provided her expertise on literature search strategies and taught me about the process. Her skills, efficiency, and organization built a strong foundation for this systematic review.

I would also like to thank my committee members, Dr. Jennifer Abbass Dick and Dr. Daniela Malta, for sharing their insight which enabled my thesis to be the best it can be. Further, I greatly appreciate that they did not allow delays or tight timelines to keep me from progressing.

Thank you to the incredible individuals that make up the Arcand Lab as well. I would particularly like to acknowledge the efforts of Bridve Sivakumar, Temitope Ayodele, and Jacqueline Brown who helped me immensely through the more time-consuming stages of the systematic review process. Further, Beatriz Franco Arellano and Katherine Jefferson gave me helpful tips without which I would not have known where to begin the daunting tasks involved in thesis writing. Last, but certainly not least, I would like to acknowledge Kori Lichtfuss for checking in on me, cheering me on, and giving me much needed side projects when I hit roadblocks with my own writing and needed to step away.

I also owe a great deal of gratitude to my family and friends for their constant support. I would like to thank my fiancé, Max, for always being by my side and pushing me to do my best no matter how discouraged I may have felt at times. I appreciate that my father,

Douglas Thom, is always willing to provide me with a fresh perspective by reading and providing feedback on everything I write. He is someone I can talk through my ideas with and is always willing to help me through whatever challenges I face. I am extremely grateful for his support. I will also be eternally grateful for my grandmother, Margaret Thom, who made me believe that I could do anything no matter how ambitious my ventures seemed at the time. Although you will not be able to read my work, I know you would have been incredibly proud and taken the time to read every word if given the opportunity.

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List of Abbreviations

AHA/ACC	American Heart Association/American college of Cardiology
ASA24	automated self-administered 24-hour tool
BP	blood pressure
CAD	coronary artery disease
CCHS	Canadian Community Health Survey
CCS	Canadian Cardiovascular Society
CDC	Centers for Disease Control and Prevention
CHD	coronary heart disease
CVD	cardiovascular disease
DALYs	disability-adjusted life-years
DASH	Dietary Approaches to Stop Hypertension
DBP	diastolic blood pressure
FFQ	food frequency questionnaire
FV	fruit and vegetable consumption
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
HF	heart failure
H-SCALE	Hypertension Self-Care Activity Level Effects

HTN	hypertension
MAP	mean arterial pressure
MDS	Mediterranean diet score
NCDs	Non-communicable diseases
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT	randomized controlled trial
RoB 2	risk of bias tool for randomized trials
RoB	risk of bias
ROBINS-I	risk of bias in non-randomized studies of interventions
SBP	systolic blood pressure
SCHFI	Self-care Heart Failure Index
SMS	short message service
STEPS	surveillance of noncommunicable diseases
TPB	Theory of Planned Behaviour

Chapter I: Introduction

Cardiovascular disease (CVD) is one of the most common non-communicable diseases. It is responsible for approximately 30% of all deaths globally (Lennon et al., 2018) and is associated with high morbidity, mortality, and healthcare expenditures (Afshin et al., 2019; Tran et al., 2016). Hypertension (HTN), coronary artery disease (CAD), and heart failure (HF) contribute greatly to this burden (Government of Canada, 2017; Padwal et al., 2016; Tran et al., 2016).

Dietary modification is a key modifiable risk factor and a core therapy for patients with HTN, CAD, and HF (Ezekowitz et al., 2017; Pearson et al., 2021; Rabi et al., 2020). For example, clinical practice guidelines for HTN prevention and control emphasize dietary sodium reduction, a diet rich in potassium and the Dietary Approaches to Stop Hypertension (DASH) diet which promotes increased intake of fruits, vegetables, whole grains, low-fat dairy, and plant proteins (Smolin et al., 2015). Sodium restriction is also recommended for patients with HTN to reduce blood pressure (BP) and prevent the onset of more serious conditions (Rabi et al., 2020). In contrast, the Mediterranean diet is encouraged for patients with CAD as it has been shown to reduce dyslipidemia and protect against atherosclerosis and CAD; the low-glycemic index and plant-based diets are also recommended and considered beneficial for the secondary prevention of CVDs (Pearson et al., 2021). In advanced heart disease, patients with heart failure are advised to restrict fluid and sodium intake to decrease hospitalizations and mortality rates (Hunt et al., 2009). These dietary recommendations are effective at improving clinical outcomes; however, dietary adherence remains a major a challenge and a barrier to the secondary prevention of these conditions (Leon et al., 2015; Ling et al., 2020; Maugeri et al., 2019).

Nonadherence to diet is a common challenge. Tugault-Lafleur and Black (2019) and Hosseini et al. (2019) showed that adherence to DASH and Mediterranean diet components are low among Canadians with a 12% reduction in fruit and vegetable consumption and less than 20% of total grain intake coming from whole grains from 2004 to 2015. Among the global population, only 40%, 57% and 24% of the recommended vegetable, fruit, and whole grain intakes, respectively, are consumed (Afshin et al., 2019). Despite having a clinical therapeutic need for specific diet prescriptions, dietary nonadherence is also common among those with CVDs, which impedes the diets' effectiveness for secondary prevention. In a study following the diet of 150 patients with hypertension, only 20% adhered to the DASH diet components over a one-month period (Leon et al., 2015). Adherence to sodium intake guidelines is also a challenge. Shi et al. (2011) stated that approximately 30% of patients with hypertension reported that they do not follow sodium intake guidelines. Further, a prospective cross-sectional study measuring dietary intake among Canadian patients with HF, found that 55% of the participants consumed excess sodium (Arcand et al., 2009). Nonadherence to key components of dietary recommendations for the secondary prevention of CVD is attributed to several factors.

The main documented contributors to dietary nonadherence in patients with CVD are lack of knowledge, the higher cost of healthy foods, lack of social support, and not considering diet a priority (Ling et al., 2020). It can also be particularly difficult for physicians to support patients with dietary recommendations when they leave the clinical setting. Additionally, dietary adherence may wane over time. Riegel et al. (2019) showed that, when patients with HF first left the hospital setting, adherence to dietary

recommendations reduced from 45% immediately after discharge to 29% 12 weeks post-discharge. Thus, it is critical to identify strategies that can address these barriers that patients with CVD face, since they can greatly benefit from the advantages of adhering to dietary recommendations.

mHealth interventions are promising supportive tools to support patients with CVD with dietary modification. mHealth interventions are defined as those that aim to improve health through a mobile device (Rehman et al., 2017). Websites, emails, text-messaging, and mobile applications can be used to educate patients about self-care and the benefits of certain recommendations (e.g., diet, exercise, and medication), remind patients to participate in health behaviours, and provide overall guidance with managing their condition (Rehman et al., 2017). For people with HTN, websites, emails, and texts have been shown to help with reaching BP-related health behaviour goals through self-monitoring and feedback (Rehman et al., 2017). Mobile applications can help improve dietary knowledge and provide social support, for example, by keeping physicians updated on their patients' health and allowing feedback (Baek et al., 2018; Naimark et al., 2015). There is evidence that mHealth interventions can help address some of the barriers that patients with CVD face when it comes to nonpharmacological treatment, such as nonadherence, lack of knowledge, and lack of support (Baek et al., 2018; Rehman et al., 2017). However, the current literature fails to consolidate the research on mHealth's impact on dietary adherence in patients with CVD, as it often focuses on multiple outcomes and conditions at once. This factor limits its ability to determine which mHealth interventions, and to what extent, they are most beneficial. To determine if mHealth interventions can improve dietary adherence in patients with CVD, a systematic

review is required. Thus, the objective of this thesis research is to conduct a systematic review to determine if the use of diet-focused mHealth interventions is effective for supporting patients with CVD in adhering to dietary recommendations, while also assessing if they improve risk factors (e.g., BP) and symptoms (e.g., shortness of breath), and indices of morbidity (e.g., hospitalizations) and mortality in the studies identified.

Chapter II: Literature Review

2.1 The Burden of Cardiovascular Disease in Canada and Globally

Non-communicable diseases (NCDs) present a significant burden on the healthcare system. Cardiovascular diseases were predicted to cost $363.4 billion USD from 2016 to 2017 (Virani et al., 2021). In Canada, from 2012 to 2016, CVDs were associated with $5.5 billion in healthcare costs per year (an average of $36,641 per person) (Tran et al., 2021). CVD also caused approximately 18 million deaths worldwide in 2015 (Roth et al., 2017), with hypertension, CAD, and heart failure being among the most common (Virani et al., 2021).

Hypertension, diagnosed when BP is greater than or equal to 130/80 mmHg on three separate occasions, affects 22.6% of the Canadian adult population (Padwal et al., 2016); prehypertension precedes this condition and is diagnosed when systolic BP is from 120 to129 mmHg or diastolic BP is from 80 to 89 mmHg (Svetkey, 2005). Over 10% of Canadian healthcare costs (about $13 billion) are attributed to hypertension management (Padwal et al., 2016). Hypertension is also responsible for 7% of the years of life lost from disability since it can progress to more serious cardiovascular (e.g., myocardial infarction) and cerebrovascular (e.g., stroke) conditions (Padwal et al., 2016; Rabi et al., 2020). Despite the serious consequences associated with hypertension, Padwal et al. (2016) found that more than 30% of individuals have uncontrolled hypertension. For every 20-mmHg increase in systolic BP and 10 mmHg increase in diastolic BP, one's risk of dying from CVD is doubled, due to CAD, heart failure, and stroke; this increase in BP must be consistent (Padwal et al., 2016; Smyth et al., 2015).

CAD is a more progressive form of CVD, which contributes greatly to the burden on the healthcare system (Government of Canada, 2017). CAD is defined as the presence of atherosclerosis in the coronary arteries. Bauersachs et al. (2019) estimated that there are approximately 154 million people living with CAD globally. The Canadian Chronic Disease Surveillance System highlighted that approximately 8% of Canadians (2.4 million people) were diagnosed with CAD from 2012 to 2013 (Government of Canada, 2017). Further, in the US this condition caused 360,900 deaths in 2019 alone and, in Canada, caused over 33,176 deaths in 2020 (CDC, 2022; Statistics Canada, 2022).

Another progressive form of CVD with high mortality rates is heart failure. Heart failure is a complex syndrome that restricts ventricular filling and ejection, resulting in symptoms of shortness of breath, fatigue, and swelling of the peripheral tissues (Hunt et al., 2009). Heart failure also puts significant financial strain on the healthcare system as it is associated with frequent hospitalization. A study by Tran et al. (2016), who analyzed data from the Canadian Institutes for Heath Information Discharge Abstract Database, estimated that annual heart failure hospitalizations would increase from 45,000 in 2013 to 54,000 by 2030. The authors also found that the costs of in-hospital care for heart failure was $482 million in 2013 and is projected to cost up to $722 million in 2030 (Tran et al., 2016).

2.2 Dietary Recommendations for Common Cardiovascular Diseases

A commonality among hypertension, CAD, and heart failure is that diet is a major modifiable risk factor for both primary and secondary prevention (Ezekowitz et al., 2017; Pearson et al., 2021; Rabi et al., 2020). On a global level, an estimated 55% of the 10 million deaths caused by CVDs were due to dietary factors (Afshin et al., 2019). Diet is

considered a key supporting therapy to manage hypertension, CAD, and heart failure, alongside medical and surgical therapies (Ezekowitz et al., 2017; Pearson et al., 2021; Rabi et al., 2020) . Adherence to diet is defined as how closely a person follows a healthcare provider's advice on diet recommendations (World Health Organization, 2003).

2.2.1 Hypertension

A primary recommendation for hypertension is dietary sodium reduction. The Hypertension Canada clinical practice guidelines recommend that sodium intake should be limited to 2000 mg or less per day (Rabi et al., 2020). The physiologic rationale for dietary sodium reduction is that excess sodium intake increases peripheral resistance and impairs endothelial-dependent vasodilation (Grillo et al., 2019). Results from a systematic review and meta-analysis of 37 RCT studies that analyzed the effects of sodium on BP showed that sodium intake of less than 2000 mg/day lowered systolic BP by 3.47 mmHg (95% CI: 0.76 to 6.18 mmHg) and diastolic BP by 1.81 mmHg (95% CI: 0.54 to 3.08 mmHg) (Aburto et al., 2013). These findings are supported by a meta-analysis which reported that, when consumption of sodium is between 2300 and 4100 mg/day, a reduction of 1000 mg/day can reduce systolic BP by 2.8 mmHg (95% CI: 1.6 to 4.0 mmHg) and reduce diastolic BP by 1.2 mmHg (95% CI: 0.5 to 1.9 mmHg); high strength evidence was found in 21 RCTs for the data on systolic BP and in 20 RCTs for the data on diastolic BP (National Academies of Sciences, 2019). There are also other dietary factors linked to improvements in hypertension. While calcium and magnesium supplements should be avoided, increased dietary potassium and the DASH diet pattern are encouraged by the Hypertension Canada (Rabi et al., 2020). The DASH diet pattern is

comprised of fruits, vegetables, whole grains, low-fat dairy, and plant proteins allowing for focus to be placed on multiple dietary components at once (Smolin et al., 2015). In a meta-analysis of 20 studies, the DASH diet showed a decrease in systolic BP by 5.2 mmHg (95% CI: – 7.0 to – 3.4; $P < 0.001$) and diastolic BP by 2.6 mmHg (95% CI: – 3.5 to – 1.7; $P < 0.001$) (Siervo et al., 2015). Total cholesterol was also reduced by an average of 0.20 mmol/l (95% CI: – 0.31 to – 0.10; $P < 0.001$). Importantly, when a low sodium diet was combined with the DASH diet, systolic BP was significantly lower for patients with hypertension compared to a control diet with high sodium (133 vs. 121.5 mmHg, $P < 0.001$). The DASH diet is also estimated to decrease incidence of CAD, stroke, and all-cause mortality by 15%, 27%, and 22%, respectively (Sacks et al., 2001; Schwingshackl et al., 2018).

2.2.2 Coronary Artery Disease

There are multiple recommendations for the management of CAD. The Canadian Cardiovascular Society (CCS) primarily recommends statin medications, frequent physical activity, and dietary patterns for reducing the progression of CAD (Pearson et al., 2021). The CCS and American Heart Association/American College of Cardiology (AHA/ACC) emphasize the intake of fruits and vegetables, whole grains, fish, nuts, and moderate amounts of low-fat dairy products, minimal refined grains, sugars, and red meats (Pearson et al., 2021; Van Horn et al., 2016). In general, the AHA/ACC recommends that about 32% of total energy intake should come from monounsaturated and polyunsaturated dietary fats, and 32 g/d of fiber should come from fruits, vegetables, and whole grains as these coincide with the Mediterranean diet which the CCS also recommends (Pearson et al., 2021; Van Horn et al., 2016). The DASH, low-glycemic

index, and plant-based diets are other key dietary patterns that promote the recommended dietary components and can have equally beneficial effects on cardiovascular outcomes (Pearson et al., 2021). Together, these dietary recommendations aim to prevent dyslipidemia and the progression of atherosclerosis (Pearson et al., 2021).

Randomized controlled trials have also demonstrated the benefits of the Mediterranean diet (Estruch et al., 2018; Tuttolomondo et al., 2019). The PREDIMED study followed 7,447 participants at high risk for CVD for an average of five years to compare participants consuming the Mediterranean diet supplemented with extra-virgin olive oil and nuts with participants advised to limit dietary fat intake (Estruch et al., 2018). Overall, it was found that adherence to the Mediterranean diet can reduce the risk of major cardiovascular events (Estruch et al., 2018). Specifically, the Mediterranean diet showed a reduction in the risk of stroke by 35% to 46% compared to the control diet depending on supplementation with extra-virgin olive oil or nuts, respectively (Estruch et al., 2018). This effect was likely due to the reduced production of foam cells (i.e., macrophages that consume low-density lipoprotein and generate plaques that restrict blood flow), decreased arterial stiffness, and decreased BP (Tuttolomondo et al., 2019).

2.2.3 Heart Failure

The primary dietary recommendation for heart failure patients is a low sodium diet and restriction of fluids, to reduce symptoms associated with sodium and fluid retention (Ezekowitz et al., 2017). Sodium should be restricted to <2000 mg per day and fluids to about 2 L per day (Ezekowitz et al., 2017). A reduction in sodium and fluid intake to the recommended levels has been shown to reduce breathlessness, edema, and

overall cardiac strain (Hunt et al., 2009). These benefits are seen more frequently when there is long term adherence to the dietary recommendations (Fonarow et al., 2008).

Dietary nonadherence has been associated with rehospitalization for patients with heart failure (Miro et al., 2018). Miro et al. (2018) found that patients with heart failure were less likely to be re-hospitalized when adherent to the Mediterranean diet (HR = 0.76, 95% CI: 0.62 to 0.93). Further, in a prospective follow-up study, Arcand et al. (2011) found that the hazard ratio for acute decompensated HF was 2.55 (95% CI: 1.61-4.04, $P < 0.001$) when sodium intake was 3.8 ± 0.8 g sodium/day compared to lower intakes of sodium (i.e., an average of 1.4 ± 0.3 and 2.4 ± 0.3 g sodium/day).

2.3 Dietary Adherence in Cardiovascular Disease

Adherence to dietary recommendations can reduce morbidity and mortality rates, and lower healthcare costs related to CVD prevention and management. Approximately 11% of deaths from CAD were a result of high intake of saturated and trans fats (Wang et al., 2016). A systematic review analyzing the relationship between mortality and adherence to 8 components of the DASH diet, with a scoring system from 8 (lowest adherence) to 40 (high adherence), concluded that every 5-point increase in adherence decreased risk of CVD mortality by 4% (95% CI: 2% – 5%) and stroke mortality by 3% (95% CI: 2% to 4%) (Soltani et al., 2020). Further, if just 50% of the population with CVD adhered to the Mediterranean diet, Abdullah et al. (2015) showed that there could be a total decrease in annual healthcare costs of up to $39.9 million in Canada due to cost savings in hospital visits, medications, and physicians' consult time (Abdullah et al., 2015). Strategies to support dietary adherence in those with hypertension and CAD are needed to maximize the health and economic benefits of dietary modification.

The DASH and Mediterranean diet patterns recommend fruits, vegetables, and whole grains as key components. Using data from the Canadian Community Health Survey (CCHS), Tugault-Lafleur and Black (2019) concluded that, from 2004 to 2015, Canadian intake of fruits and vegetables has decreased by approximately 12% while consumption of meat and alternatives has increased by approximately 10% ($P < 0.05$). Another study analyzing the same data determined that approximately 60% of Canadian adults consumed less than 20% of their total grain intake from whole grains (Hosseini et al., 2019). Globally, the population only consumes about 40% of the recommended vegetable intake, 57% of the recommended fruit intake, and 24% of the recommended whole grains intake (Afshin et al., 2019). Better adherence to these dietary components is needed to prevent the onset and progression of hypertension and CAD.

Excess sodium intake is another key public health challenge. Approximately 30% of Canadians with hypertension do not adhere to sodium intake guidelines, with average intakes of sodium being approximately 2950 mg/day (95% CI: 2810 – 3090 mg/day) (Shi et al., 2011). Adherence to a low sodium diet is a challenge for patients with heart failure as well. Only 50.6% (n = 120/237) of patients with heart failure self-reported in a dietary questionnaire that they *always* adhere to dietary sodium guidelines (Colin-Ramirez et al., 2015). Additionally, adherence rates decrease over time. Riegel et al. (2019) showed that adherence to dietary recommendations was about 45% when the patient first left the hospital and only 29% after 12 weeks of being out of the hospital. While adherence to medication was higher at discharge (95%), it also declined after 12 weeks to 72% (Riegel et al., 2019). These findings indicate that higher emphasis may be put on medication

adherence with clinical practice guidelines and adherence to overall treatment decreases when guidance is not present (Riegel et al., 2019).

Overall, adherence rates to dietary recommendations for hypertension, CAD, and heart failure can present a major clinical challenge and increase symptom burden and rates of morbidity and mortality. Dietary components need to be emphasized to prevent the progression of these common CVDs and improve clinical outcomes for patients. Adherence to diet-focused clinical practice guidelines for patients with CVD appears to be high initially, but patients need support outside of clinical practice to effectively self-manage their diet.

2.4 Barriers to Dietary Adherence

Considering the socio-ecological model, there are several policy-level and environmental factors that impact the availability and access to food, including the quality, availability of foods, and cost (Story et al., 2008). Restaurants are easily accessible and serve foods that tend to be higher in calories, fat, and sodium (Murphy et al., 2020), but there are no policies requiring them to publicly display nutritional information (Story et al., 2008). Although home-made meals are a healthier alternative to prepared foods, rural and remote communities may have limited access to supermarkets with fresh and unprocessed foods (Story et al., 2008). Cost can also limit food choice, especially in low-income households (Story et al., 2008). The reason processed foods are a cheaper and more readily available alternative is due to some policies and programs funding the overproduction of the crops that are required to produce them (Story et al., 2008). Individual and social factors can also contribute to the challenges of eating healthier foods.

One of the largest barriers to chronic disease management is a lack of adherence to behavioural changes (Rodriguez et al., 2019). For patients with CVD, maintaining a diet that coincides with professional recommendations for an extended period is difficult (van der Wal & Jaarsma, 2008). Considering the Theory of Planned Behaviour (TPB), a person with high self-efficacy (e.g., food skills, and food and health literacy) is more likely to engage in behavioural changes (McDermott et al., 2015). The TPB additionally suggests that certain attitudes, subjective norms, and perceived control further influence health behaviour change (Taylor et al., 2017). To support dietary changes, patients need to have knowledge that the diet will be beneficial, believe their peers want them to change their diet, and have confidence they can maintain the diet (Taylor et al., 2017). These factors are common barriers to dietary adherence among patients with CVD.

Although knowledge alone does not guarantee adherence, a lack of knowledge about the benefits of certain diets is a documented barrier among patients with hypertension and heart failure (Bentley et al., 2005). A qualitative study by Bentley et al. (2005) found that the main reasons for non-adherence to diet among patients with heart failure are lack of knowledge regarding which foods meet the recommended diet, not being able to find and purchase foods that meet the recommendations, and not having enough low sodium options available to them. These findings were supported by a cohort study among patients with hypertension, which determined that participants with lower levels of formal education were less likely to think dietary adherence was a priority (Shim et al., 2020). Leon et al. (2015) also found that adherence to the DASH diet was five times more likely among patients with more hypertension knowledge. As suggested

by the TPB, knowledge about the intended health behaviour is essential for successful behaviour change (Taylor et al., 2017).

Further barriers include those related to social support. Ling et al. (2020) performed a cross-sectional study of factors associated with dietary adherence in patients with heart failure. The study concluded that dietary adherence can be difficult in low-income households because of limited availability of low-cost foods that correspond to dietary recommendations (Ling et al., 2020). Ling et al. (2020) also found that patients are more likely to adhere to diets when they have social support as it is correlated with self-care; a lack of social support is a barrier to dietary adherence. This barrier is also common for patients with CAD. Maugeri et al. (2019) found that people were about three times more likely to adhere to the Mediterranean diet if they lived with family.

Overall, current literature shows that dietary adherence is dependent on knowledge, social support, and self-efficacy. Tools are needed to reinforce the primary components of the TPB to promote dietary adherence through behavioural change in patients with CVD.

2.5 Strategies to Improve Adherence in Cardiovascular Disease: The Role of mHealth

Various healthcare professionals, such as physicians, nurses, and dietitians, are involved in the management of CVD, which can include providing education and monitoring of diet. However, physicians and nurses are the front-line providers and often have limited time during clinical visits to provide dietary recommendations (Yu et al., 2018). For example, Dash et al. (2020) found that 76.3% of Canadian primary care physicians do not believe they have enough time to discuss diet with their patients. There

may also be a lack of formal education on nutrition counselling (Pallazola et al., 2019). Dash et al. (2020) also reported that 65.8% of Canadian primary care physicians believed more nutritional education to medical students would facilitate their ability to fully advise patients with hypertension. Due to these circumstances, dietitians are often consulted to provide tailored dietary counselling. However, individualized counselling may still not be feasible for all patients within the health system especially with limited availability of dietitians in rural and remote communities (Pallazola et al., 2019). This limitation highlights a need for novel strategies to support patients in dietary adherence through education and monitoring. One emerging strategy is mHealth.

2.5.1 mHealth Interventions

With chronic diseases becoming an increasing burden, mHealth interventions have been identified by the World Health Organization as a potential solution for the barriers to adherence to treatment regimens (World Health Organization, 2011). mHealth interventions are defined as those that aim to improve health through a mobile device such as websites, emails, text messages, health trackers, and mobile applications (Rehman et al., 2017). mHealth interventions can provide patients with education, support, or an accessible tool to self-manage their condition, which coincides with behavioural theories, including the TPB (Rehman et al., 2017). Further, the use of technology is on the rise (Government of Canada, 2018; Schuuring et al., 2016; Treskes et al., 2019). For example, the majority of Canadians have access to internet (87.4%) and smartphones (87.9%), and multiple studies have shown that >70% of patients with CVD are willing to use mHealth (Government of Canada, 2018; Schuuring et al., 2016; Treskes et al., 2019). Clinicians have also demonstrated acceptability of mHealth in clinical

practice settings. A qualitative study by Laing et al. (2021) reported that healthcare practitioners feel that mHealth could assist patients with adhering to treatment, be easily integrated into daily routines, help with tracking patient data, and remove communication barriers (e.g., language). The versatility of mHealth and wide availability of technology suggests that mHealth may provide impactful tools to reinforce clinical dietary recommendations for patients with CVD.

mHealth interventions can also provide more accessible healthcare for patients with CVD, especially those with heart failure. Patients with heart failure require specialized care, which is difficult to obtain in rural and remote communities (Anand et al., 2019). This challenge was documented in nine First Nations communities in Canada, where over 20% of the population, who lived in one of these communities, had difficulty accessing healthcare (Anand et al., 2019). Although mHealth may not be accessible to all in remote or rural communities, the majority of Northern communities in Canada have access to cellular networks; the Government of Canada (2018) reported that 63.5% of the North has access to long-term evolution (LTE) networks. Due to high healthcare costs, demand for resources, and limited access to healthcare for some CVD patients, it is therefore critical to examine more accessible tools, such as mHealth tools, that may be able to help with self-management and promote diet adherence.

2.5.2 Website, Email, and Text-Based mHealth Interventions

There is evidence suggesting that mHealth in the form of websites, emails, and text messages are effective for chronic disease management (Rehman et al., 2017). An RCT showed that text messaging can improve adherence to dietary recommendations for 6 months compared to a control group (93% vs. 75%, $P < 0.001$) (Santo et al., 2018). A

systematic review, which analyzed five studies about the effects of mHealth on BP in patients with hypertension, reported that e-mail and website-based feedback about BP led to 22% more participants showing a decrease in systolic BP vs. 17% in the control group ($p = 0.02$). The same study also reported 29% more people exhibiting a significant decrease in diastolic BP vs. 16% in the control group ($p = 0.03$) (Rehman et al., 2017). Text reminders to check BP, used in two of the five studies, led to significantly improved BP control among participants receiving the intervention, compared to a control group (77% vs. 12%, $P < 0.001$) (Rehman et al., 2017). However, one of the five studies showed no significant improvement in BP with text messaging when it was used to educate participants with hypertension about their condition and test their knowledge on health behaviours. Overall, the systematic review by Rehman et al. (2017) indicates that different forms of mHealth, which educate patients on CVD management, provide ways of monitoring BP, and send reminders about medication, can be beneficial for lowering BP in patients with hypertension. Although this shows promise for mHealth, this review did not examine the effects of mHealth on dietary adherence in patients with CVD.

Other systematic reviews (n = 2) have analyzed the effectiveness of solely text-based mHealth interventions for medication adherence and clinical outcomes of chronic diseases (Hamine et al., 2015; Palmer et al., 2021). A 2015 systematic review assessed 107 studies that examined the effects of text messages on adherence to medication for patients with diabetes, CVD, or chronic lung diseases (Hamine et al., 2015). Of the 107 studies analyzed, only 27 focused on CVD, and of these, five showed significant improvement in medication adherence and seven showed significant improvements in clinical outcomes for participants using a text messaging mHealth intervention (Hamine

et al., 2015). A more recent systematic review found similar results, with five of six studies reporting increased medication adherence among participants using text-based mHealth vs. a control group (83.3% vs. 79.2%, $p = 0.006$) (Palmer et al., 2021). These results indicate that text-based mHealth can result in behavioural changes, in this case medication adherence. Since these systematic reviews only analyzed the effects of text-based mHealth on medication adherence, it remains unclear, yet promising, as to whether website, e-mail, and text-based mHealth can improve dietary adherence for patients with CVD. Overall, the systematic reviews published, to date, have not examined the impact of mHealth interventions on behavioural changes, such as dietary adherence, as a key mechanism leading to improved health outcomes.

2.5.3 mHealth Mobile Applications

A prevalent mHealth intervention delivery mode is mobile applications due to their versatility and accessibility. Mobile applications for smartphones and tablets can be used for education, monitoring health behaviours, communicating with health professionals, and/or managing clinical symptoms of various conditions (Baek et al., 2018). In a 2018 study, 94% of patients stated that they would be interested in using mobile applications to assist with CVD management (Baek et al., 2018). Participants also indicated, using a 5-point scale, that physician advice (4.77), risk assessments (4.46), and exercise management (4.40) were features that patients with CVD thought were most useful (Baek et al., 2018). Other features that were deemed important were education (4.23), BP measurement (4.17), health status (4.11), and dietary support (e.g., diet logs and information) (3.91). The latter indicates that dietary adherence may not be as high of a priority for patients with CVD as it should be compared to other aspects of disease

management. When asked, only 60% of participants believed diet was important and 49% focused on diet as part of their CVD management (Baek et al., 2018). However, this study shows that people will likely use and trust mHealth applications. Further, mobile application interventions might be a useful medium for conveying the importance of diet and include features that help the patient adhere to it.

There is encouraging evidence indicating that dietary adherence can be improved using mHealth applications. An RCT by Choi et al. (2019) used the Mediterranean diet score (MDS) to measure adherence (14-point scale with which a score of 9 or higher is considered high adherence) to the dietary recommendations for CAD with standard care versus a mobile app that could be used to contact a dietitian and track diet. There was an increase in the proportion of participants with high adherence to the Mediterranean diet from 28% to 65% in the group using mobile applications, compared to an increase of 18% to 57% in the standard of care group ($P < 0.001$) (Choi et al., 2019). A quasi-experimental study also showed improved dietary adherence for participants at risk for heart disease who used an app that allowed for goal setting and informed the participant on the risk of cardiovascular events based on health behaviours (Kwon et al., 2020). Over the 4-week study period, participants had significantly improved diet quality scores, with a higher score indicating higher consumption of fruits, vegetables, nuts, and white meat (2.36 vs. 1.31, $p = 0.008$) (Kwon et al., 2020). Other studies have shown that mobile apps can produce dietary changes in patients with CVD as well (Debon et al., 2020; Dorsch et al., 2020). Although evidence suggests mHealth applications can assist patients with CVD adhere to dietary recommendations, there are currently no systematic reviews to consolidate this data.

Other studies on the use of mHealth applications for dietary adherence contain inconsistencies related their quality and results. An RCT by Spring et al. (2018) showed an increase in fruit and vegetable consumption of 6.5 servings per day and decrease in saturated fat intake by 3.6%. These results were maintained for 9 months indicating high adherence to diet with mobile apps; however, an incentive of $5 was given to the intervention group if the participants maintained the desired health behaviours, limiting generalizability of the results to "real world" settings. Another RCT, indicating that a mobile app called SaltSwitch can improve diet for patients with CVD, showed no differences between groups (Eyles et al., 2017). Eyles et al. (2017) showed that such app could reduce sodium consumption by about 0.7 g/day, but there was no significant difference when compared to the control group. This lack of difference may be due to the researchers requiring participants to hand in grocery receipts to track dieting and all receipts may not have been submitted for review (Eyles et al., 2017). An up-to-date systematic review could assess the totality of evidence, including its quality, and improve understanding on whether mHealth applications can effectively increase dietary adherence among CVD patients.

Furthermore, past systematic reviews that focus on mHealth interventions have important gaps, including not focusing on the individual forms of CVD, and analyzing the effects on healthier populations or isolated cohorts. Schoeppe et al. (2016) identified twenty-seven studies that focused on using mHealth interventions to support healthy diet, physical activity, and sedentary behaviours in children and adults. The authors highlighted that, of thirteen studies analyzing the impact of diet, only seven studies found a significant impact on health outcomes. This systematic review only examined studies

that included healthy participants with mobile apps acting as a primary prevention tool; therefore, it is unknown if similar findings would be observed in CVD patient populations. In contrast, Park et al. (2016) identified 28 studies that evaluated secondary prevention of CVD and, although 79% of the studies showed improvements in behavioural changes and clinical outcomes, none of the included studies focused on dietary adherence. In contrast, Changizi and Kaveh (2017), who only examined articles on the effects of mHealth interventions in elderly patients with CVD, found that mHealth significantly improved dietary habits. Current evidence on the effectiveness of mHealth is encouraging; however, there is inconclusive literature on the use of mHealth for dietary adherence and the prevention of specific CVDs, where diet can be a major modifiable risk factor.

2.6 Conclusion

Overall, dietary recommendations are a core component of CVD management, however dietary adherence can be a major challenge for patients with CVD. Research shows that mHealth may be an effective tool for supporting health behaviour changes, such as healthy eating and increased dietary adherence. When studies do include the measurement of diet, it is only a minor component of an mHealth intervention evaluation; however, there is no consolidated understanding in the literature of the full impact of mHealth interventions on dietary adherence. Existing systematic reviews have not made this element a primary focus, and have only examined specific sub-populations, such as seniors. It is therefore important to further the current understanding of mHealth interventions and answer the question, “can mHealth applications improve dietary adherence in adults with CVD versus standard clinical practice?”. Determining which

types of mHealth interventions, if any, are helpful for dietary adherence among patients with CVD may provide this population with a tool that leads to less reliance on physicians.

Chapter III: Objectives

Although diet is a key component for the management CVD, there is no consolidated understanding on whether mHealth interventions can be recommended as supportive tools to aid patients in adhering to dietary prescriptions. Thus, the primary objective of this research is:

1. To determine if diet-focused mHealth applications are effective for supporting patients with CVD (hypertension, CAD, and heart failure) in improving adherence to dietary recommendations (primary outcome).

Additionally, secondary objectives include:

2. To determine if the use of diet-focused mHealth applications in the identified studies can improve other cardiovascular risk factors (e.g., BP, lipid biomarkers) and symptoms (e.g., shortness of breath, edema) (secondary outcome).
3. To determine if using diet-focused mHealth applications, in the identified studies, can improve indices of morbidity and mortality, such as decreased hospitalizations caused by heart failure.

Chapter IV: Methods

4.1 Study design

A systematic review was conducted, including articles from 2007 to September 16, 2021, according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist (Moher, 2015). The systematic review was registered with Prospero and is designed to address both primary and secondary outcomes. Since no human participants were included and no secondary data was used, research ethics board approval was not required.

4.2 Search Strategy

The Ovid-Medline, Ovid Cochrane, CENTRAL, CINAHL, Ovid EMBASE, Scopus, Web of Science, ProQuest Dissertations & Theses Global and Ovid PsycINFO databases were used to identify relevant literature. Due to their extensive health sciences literature, these databases were expected to provide the most results related to mHealth and dietary adherence. To further ensure that all relevant literature was identified, grey literature was searched using reliable databases such as the Public Health Grey Literature Database, and citation lists within identified papers and related systematic reviews were examined. The search terms were identified by extracting relevant terms from the research question and doing a preliminary search in Ovid-Medline to find common synonyms. A medical librarian assisted with refining the search terms and strategy. Boolean searching was done by connecting related terms with “or” and groups of related terms with “and”; all forms of CVD were combined with “or”; the search strategy is outlined in Appendix 1. Once the search was complete, inclusion and exclusion criteria were used to ensure only the most appropriate studies were included in the systematic review.

4.3 Inclusion and Exclusion Criteria

Inclusion and exclusion criteria were developed using the PICO model (Table 1). Articles that included patients with a diagnosis of pre-hypertension, hypertension, CAD, and heart failure (reduced or preserved ejection fraction) were included. Articles were only included if they were published after the production of smartphones (2007) which enable access to mHealth (World Health Organization, 2003). The types of mHealth interventions included were emails, websites, text messages, and mobile applications. Since there are a wide array of mHealth features that have been shown to be beneficial (Baek et al., 2018), all app purposes and features were considered as long as the app was designed to support patients with CVD, including educational apps, those that physicians can use to provide feedback to the patient, and apps paired with trackers (monitoring apps). Studies had to have measures of dietary adherence (primary outcome). Studies that measured the secondary outcomes were only included if they also measured the primary outcome. Studies using multi-component mHealth interventions (e.g., mHealth assessing physical activity, medication, and diet) were included only if dietary adherence was measured. Types of studies included were randomized control trials (RCTs), non-randomized trials, and app development studies (i.e., usability and proof-of-concept studies); qualitative studies, and systematic reviews with and without meta-analyses were excluded. Only studies published in English were included as well as studies that could be effectively translated to English. Finally, studies that examined pediatric participants (less than 18 years of age) were excluded to reduce heterogeneity that could have been introduced by including this population.

Table 1. *Article inclusion and exclusion criteria*

	Inclusion	**Exclusion**
Population	• Patients with a diagnosis of pre-hypertension, hypertension, CAD, or heart failure (reduced or preserved ejection fraction) • Adults (≥ 18 years old)	• Children and Adolescents
Intervention	• mHealth in the forms of mobile applications, websites, emails, and text messages • Multi-component mHealth	• Telehealth (phone calls) • Live interaction or the ability to have open dialogue between researcher and participant
Outcomes	Primary Outcome: • Dietary adherence Secondary Outcomes: • Clinical risk factors and symptoms • Indices of morbidity and mortality	• No measures of dietary adherence
Language	• English	• Non-English studies that cannot be effectively translated
Study Design	• Quasi-experimental • Randomized • App development (i.e., usability and proof-of-concept studies)	• Qualitative • Systematic reviews with or without meta-analysis

4.4 Dietary Adherence Measurements

There were multiple forms of dietary adherence measurements that were of interest during data collection. Quantitative measures of dietary adherence included food and nutrient intakes assessed using food frequency questionnaires, food records, 24-hour recall, urinary analysis (sodium, magnesium, and potassium), quantity of different foods consumed per day (e.g., mg/day or g/day), adherence rates (%), healthy eating indices, scoring associated with adherence to specific dietary patterns (e.g., the DASH score), and

other data which is consistent with the primary outcome; studies including any of these measurements were included.

4.5 Article Screening and Selection

On completion of the database searches, the titles and abstracts of identified articles were transferred to Covidence, where duplicates were automatically removed. The remaining articles were screened to determine if they met inclusion criteria. Exclusions and reasons for exclusions were tracked. As recommended in the Cochrane Handbook for Systematic Reviews of Interventions, two reviewers (a master's student and either a PhD student or fourth year undergraduate student) independently reviewed titles and abstracts, and a third reviewer resolved discrepancies if the two reviewers could not come to a consensus during each stage of the screening and selection process. Among articles that passed the title and abstract screening, full texts were uploaded into Covidence. Two independent reviewers assessed each full text to determine eligibility, with any discrepancies resolved by a third reviewer. All articles that passed full text screening were downloaded into EndNote. This process was displayed in the PRISMA flow diagram; excluded studies were shown as well as reasoning for exclusions (Pati & Lorusso, 2018).

4.6 Quality of Evidence Assessment

4.6.1 Risk of Bias Assessment

The risk of bias of eligible articles was assessed using the risk of bias tools from the Cochrane Handbook for Systematic Reviews of Interventions. For randomized studies, the risk of bias tool for randomized trials (RoB 2) was used (J. P. T. Higgins et al., 2019). This ensured that bias was accounted for in the randomized trials included.

Missing data, divergence from the original study plan, and other topics were considered with RoB 2. For non-randomized studies, the ROBINS-I tool was used. This accounted for the most prevalent forms of bias such as confounds, selection bias, information bias, and reporting bias (J. P. T. Higgins et al., 2019). A template was used to assess each study to determine the risk of bias for each topic; these topics are listed as domains in each template. To determine the risk of bias for each domain and the overall risk of bias for each study, guidance documents were used. These documents provided an algorithm that associated specific answers to specific risk of bias profiles such as high, some concerns, or low for the RoB 2 tool (J. Higgins et al., 2019) and low, moderate, critical, and serious for the ROBINS-I tool (Sterne, Higgins, et al., 2016). For each article, the risk of bias assessment was conducted by two independent reviewers. Discrepancies were discussed and be resolved by a third reviewer, if needed. Results from the risk of bias assessments were presented in a risk of bias matrix and Appendix B.

4.6.2 Grading of Recommendations, Assessment, Development and Evaluations (GRADE)

The GRADE framework was used to assess the quality of evidence related to risk of bias, inconsistency, indirectness, imprecision, and publication bias as detailed by the Cochrane Handbook for Systematic Reviews of Interventions (J. P. T. Higgins et al., 2019). A summary of the main findings was displayed in a table and narratively described.

4.7 Data Collection and Analysis

The data from the studies were collected in a table which contains the author of the study, the year and country the study was conducted in, the study design used, characteristics of the mHealth intervention, outcomes assessed and associated effect

measures, outcome measures utilized, and the results; these data were collected independently and then confirmed by a second reviewer. Specifically, results from measures of dietary adherence were reported for each study (primary outcome), and clinical outcomes and symptoms (e.g., blood pressure), or indices of morbidity and mortality (secondary outcomes), if available. The secondary outcomes of interest were chosen since these are often evaluated as part of dietary intervention studies due to the impact of diet on CVD outcomes (Pearson et al., 2021). This information was analyzed in a narrative synthesis describing the overall results and risk of bias for each study. Any missing data was reported and accounted for in the risk of bias assessments.

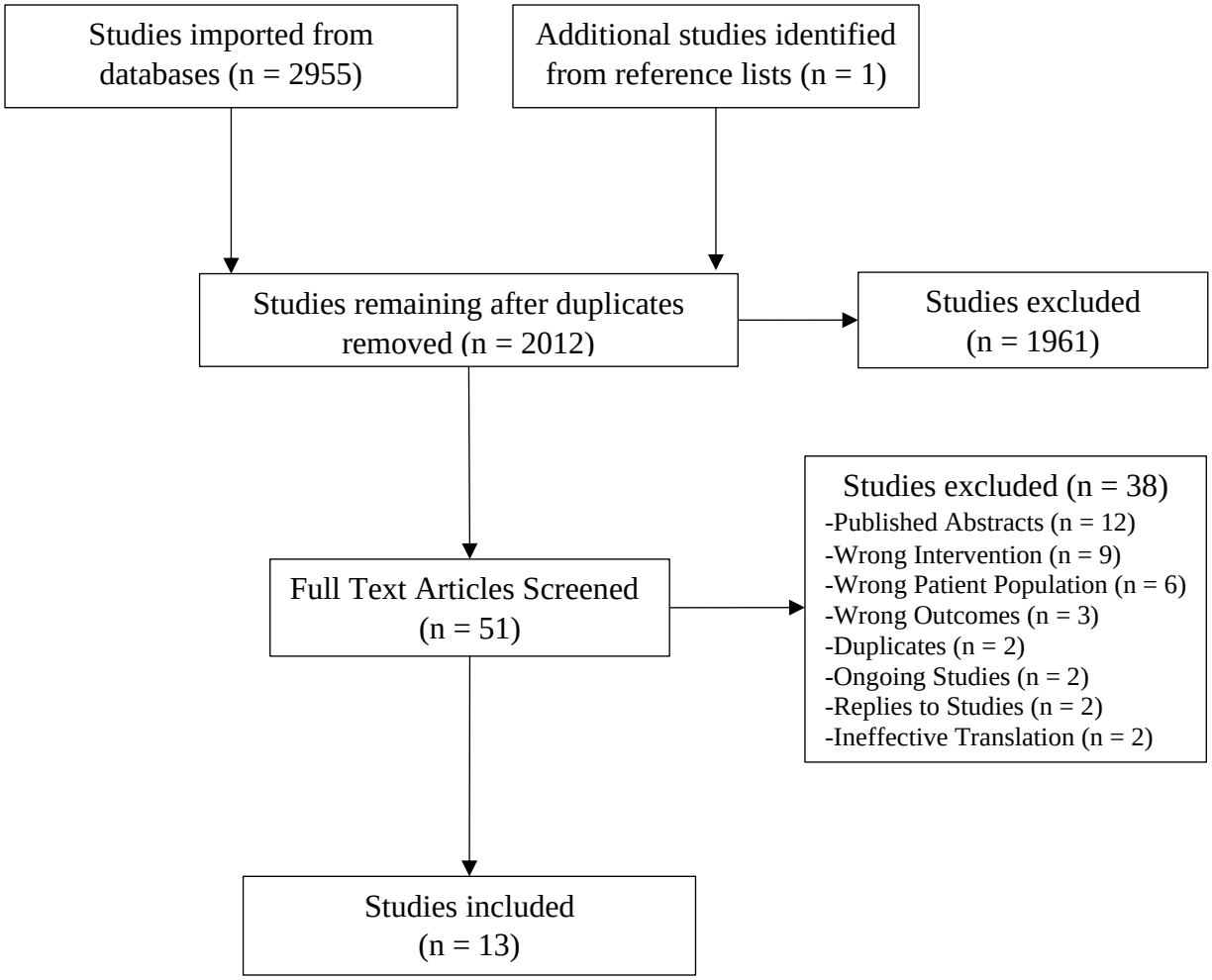
In this study, a meta-analysis would be conducted if certain criteria were met. The Cochrane Handbook for Systematic Reviews of Interventions states that there must be limited clinical and methodological heterogeneity among the included studies, limited bias, enough research in the topic of interest (i.e., more than one included study), and comparable effect measures reported in all included studies (J. P. T. Higgins et al., 2019). Clinical heterogeneity refers to variation among the population, interventions used, and outcomes of interest. Methodological heterogeneity refers to variations in study design, outcome measurements, and also includes risk of bias (J. P. T. Higgins et al., 2019).

Chapter V: Results

5.1 Included Studies

There were 2956 articles identified through database and reference list searches. After duplicates were removed, a total of 2012 articles remained for abstract screening. During abstract screening, 1961 articles were excluded due to not meeting the inclusion criteria. This left 51 articles for full-text screening from which 13 met the inclusion criteria (Figure 1).

Figure 1. *Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) flow diagram of included and excluded studies.*



5.1.1 Study Characteristics

Among the included studies, ten were RCTs and three were pre-post study designs; no usability or proof of concept studies were identified. Table 2 provides a description of each included study. There were multiple types of mHealth interventions analyzed in the included studies. The studies' intervention timeframes ranged from 1 to 12 months and included participants with varying forms of CVD, including prehypertension (n = 1), hypertension (n = 9), CAD (n = 2), and HF (n = 1). The studies were conducted in the United States (n = 5), Iran (n = 2), Canada (n = 2), China (n = 1), Palestine (n = 1), Australia (n = 1), and Jordan (n = 1).

5.2 Primary Outcome: Dietary Adherence

5.2.1 Characteristics of mHealth interventions

The mHealth interventions examined in the identified articles had various delivery modes including text messages (n = 5) and mobile apps (n = 4) or a combination of the two (n = 1). Other studies tested website-based mHealth (n = 2) and e-mails (n = 1). All interventions were focused on education (n = 13), but some also included monitoring (n = 3) and connecting patients with physicians (n = 1). Text message interventions included features such as providing information about the condition and associated treatments (n = 5), reminders to follow treatment plans (n = 2), and individualized advice to encourage behaviour change (n = 3) (Table 3). The mobile applications had information supplying (n = 4), feedback (n = 2), tracking (n = 2), and personalization (n = 4) characteristics which provided participants with an interactive intervention (Abraham & Michie, 2008). The intervention that used a combination of text messaging and mobile applications used educational and tracking features. E-mail and website-based mHealth interventions primarily had information supplying features (n = 3).

The different delivery modes had varying effectiveness on dietary adherence. Four of the five studies that used text message interventions (n = 5) showed improvements in dietary adherence (Akhu-Zaheya & Shiyab, 2017; Nundy et al., 2013; Russaw, 2014; Santo et al., 2018), based on analyses demonstrating significant between group differences over time or significant pre/post changes in dietary adherence. Among mobile app interventions (n = 4), two showed between-group improvements in dietary adherence over time (Abu-El-Noor et al., 2021; Bozorgi et al., 2021). The other two mobile app intervention studies reported mixed effects on dietary adherence, with one study conducting between-group comparisons and one using pre/post analysis only (Chen et al., 2018; Dorsch et al., 2020). The one study that used a combination of both a mobile app and text messages did not show significant between group differences in dietary adherence; yet, dietary adherence significantly improved in both groups from baseline to end of study (Steinberg et al., 2020). E-mails had mixed effects on dietary adherence (Liu et al., 2018). Further, one study showed that website-based mHealth improved dietary adherence (Staffileno et al., 2018) while another showed that website-based mHealth only had an effect on dietary adherence among females (Liu et al., 2020). It should be noted that these studies had varying comparators (seven studies used a control group, two used a placebo group or active comparator, and four did not use a comparator) which may have influenced these results.

Table 2. *Key features of mHealth interventions identified in the included literature.*

mHealth Intervention	Features
Text Messages (n = 6*)	- Reminder messages about medications and dietary recommendations (n = 2) - Educational messages about routine care and signs of disease progression (n = 3) - Individualized advice for lifestyle changes (n = 2)
Mobile Applications (n = 5*)	- Alarms and messages to remind of medications and appointments (n = 2) - Provide education about CVD and its management (n = 4) - Record BP measurements and receive feedback (n = 2) - Provide diet plans and tracking (n = 2) - Send motivational messages specific to individual needs (n = 2) - Provide low-sodium meal options at restaurants and general food alternatives (n = 1) - Send behaviour change messages when making food choices (n = 1)
E-mails (n = 1)	- Provide diet plan (n = 1) - Provide information about CVD management (n = 1) - Information about self-managing lifestyle changes (n = 1)
Website-based (n = 2)	- Videos, online handouts, and self-monitoring and self-help resources to encourage lifestyle changes (n = 1) - Online education modules about diet based on individual needs and preferences (n = 1) - Provide weekly activities and goal setting (n = 1)

*One study used a combination of text messages and mobile applications

Studies that analyzed the impact of mHealth on prehypertension, hypertension, CAD, and HF found that dietary adherence improved when the intervention was used more frequently (i.e., one or more times per week) over a shorter duration of time (i.e., one to six months) (Abu-El-Noor et al., 2021; Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Nundy et al., 2013; Russaw, 2014; Santo et al., 2018; Staffileno et al., 2018; Steinberg et al., 2020). Studies that had patients use the intervention less frequently (i.e., monthly) over a longer duration of time (i.e., eight or twelve months) showed no significant improvement in dietary adherence among all participants (Golshahi et al., 2015; Liu et al., 2020).

5.2.2 Components of mHealth interventions

Most of the included studies were focused on improving adherence to multiple types of health behaviour changes (e.g., diet, medications, physical activity, and appointments) at once, rather than focus solely on dietary behaviours. Ten of the studies used mHealth interventions which focused on improving adherence to multiple health behaviour changes whereas the remaining three only focused on improving dietary adherence. Specifically, six of the ten studies of mHealth interventions that addressed multiple lifestyle changes showed a statistically significant improvements in dietary adherence with the use of the intervention (Abu-El-Noor et al., 2021; Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Nundy et al., 2013; Russaw, 2014; Santo et al., 2018); three studies showed mixed results (Chen et al., 2018; Liu et al., 2018; Liu et al., 2020) and one study showed no improvement (Golshahi et al., 2015). In contrast, two of the three studies that examined mHealth interventions solely focused on diet showed a statistically significant improvement in dietary adherence (Staffileno et al., 2018; Steinberg et al., 2020); one study showed mixed results (Dorsch et al., 2020).

mHealth interventions were shown to produce statistically significant improvements in adherence to a variety of diets, such as low sodium diets (n = 3) (Abu-El-Noor et al., 2021; Nundy et al., 2013; Russaw, 2014), low-sodium and fat in combination with the DASH diet (n = 1) (Bozorgi et al., 2021), general recommendations for CVD prevention (e.g., increased intake of vegetables, fruits, and fish, and decreased intake of take-out meals and sodium; n = 1) (Santo et al., 2018), the DASH diet (n = 2) (Staffileno et al., 2018; Steinberg et al., 2020), and the Mediterranean diet (n = 1) (Akhu-Zaheya & Shiyab, 2017). All five studies that examined dietary patterns showed a

statistically significant improvement in adherence after the use of an mHealth intervention between the intervention and control group over time, or pre/post intervention (Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Santo et al., 2018; Staffileno et al., 2018; Steinberg et al., 2020). In contrast, there were inconsistent findings among the studies that examined the effects mHealth on adherence to single dietary components (e.g., fruits, vegetables, or sodium). Three of the eight studies that examined single dietary component interventions showed a statistically significant improvement in dietary adherence (Abu-El-Noor et al., 2021; Nundy et al., 2013; Russaw, 2014). Four of the remaining five studies showed mixed results for the effect of mHealth interventions on single dietary component intake (Chen et al., 2018; Dorsch et al., 2020; Liu et al., 2018; Liu et al., 2020) and one showed no significant improvements (Golshahi et al., 2015).

Table 3. *Description of the characteristics, and dietary and clinical outcome results identified in each included study.*

Author(s) (Country, Year)	**Study Design (Intervention Duration)**	**Population Diagnosis (age; Sample Size)**	**Intervention(s) vs. Comparator(s)**	**Outcomes Measured**	**Outcome Measurement**	**Results**
Studies that conducted between-group comparisons over time						
Liu et al. (Canada, 2020)	Parallel RCT (12 months)	HTN (35 to 74 years; IG (n = 100), CG (n = 97))	IG: E-counselling platform (28 educational sessions delivered through website-based mHealth; sent through e-mail weekly for first four months, biweekly for next 4 months, and monthly for last four months) +	*Diet* FV, sodium intake	*Diet* FV: NIH/National Cancer Institute Diet History Questionnaire (124-item FFQ) used at baseline, month 4, and month 12 to assess daily intake Sodium: 24-hour urinary sodium excretion (gold standard, single measure at baseline and after month 12)	*Diet* - Significant between group differences in urinary sodium of -23 mmol/24hr (95% CI -43.4 - -3.3) among females only (p = 0.02) - Both the control and e-counselling groups increased their FV intakes after 4 months by 0.72 servings/day (p = 0.045); however, no between group differences were observed

Author(s) (Country, Year)	Study Design (Intervention Duration)	Population Diagnosis (age; Sample Size)	Intervention(s) vs. Comparator(s)	Outcomes Measured	Outcome Measurement	Results
			routine care vs. CG: routine care alone Characteristics: educational			- No within group differences in urinary sodium were reported
Akhu-Zaheya & Shiyab (Jordan, 2016)	Parallel RCT (3 months)	HTN (≥ 18 years; IG (n = 52), PG (n = 52), CG (n = 56))	IG: Routine care + Daily reminder text messages on medication, healthy diet, and smoking cessation vs. PG: Routine care + Daily text messages about general health advice vs. CG: Routine care Characteristics: personalization, educational	*Diet* Mediterranean Diet adherence	*Diet* Mediterranean Diet Adherence Screener (MEDAS, score): 13-items (2 related to food intake habits and 11 related to food consumption frequency) to assess daily intake pre and post intervention	*Diet* - Significant difference in Mediterranean diet adherence between the three groups (p = 0.00) - Significant increase in the Mediterranean diet adherence score from 6.9 ± 1.9 to 8.86 ± 1.8 in the group that received reminder texts (p = 0.00) - Significant decrease in the mean Mediterranean diet adherence score from 7.28 ± 2 to 5.8 ± 1.97 in the group that received general texts about health advice (p = 0.00) - No change in the Mediterranean diet adherence score in the control group
Liu et al. (Canada, 2018)	Parallel RCT (4 months)	HTN (35 to 74 years; IG 1 (n = 37), IG 2 (n = 39), CG (n = 39))	IG 1: Weekly user-driven e-mails (contained a choice of lifestyle change resources; participants made their own exercise and diet goals) vs. IG 2: Weekly expert-driven e-mails (contained pre-determined exercise and diet plans) vs. PG: Weekly generic e-mails about hypertension	*Diet* FV *Other* SBP, DBP	*Diet* NIH/National Cancer Institute Diet History Questionnaire (124 items related to foods and dietary supplements) administered at baseline and month 4 *Other* BpTRU blood pressure recording device	*Diet* - Significant difference in fruit intake between the expert-driven group vs placebo (p = 0.01), and user- vs expert-driven groups (p < 0.01) - Mean increase in daily fruit intake by 2.1 (95% CI 1.3 – 2.8) servings/day in the expert-driven group, 0.1 (95% CI -0.7 – 0.7) in the user-driven, and 0.5 (-0.2 – 1.3) in the placebo group - No significant difference in vegetable intake

Author(s) (Country, Year)	Study Design (Intervention Duration)	Population Diagnosis (age; Sample Size)	Intervention(s) vs. Comparator(s)	Outcomes Measured	Outcome Measurement	Results
			Characteristics: educational			between the three groups ($p = 0.35$) *Other* - Significant difference in SBP in expert-driven group vs placebo ($p < 0.01$) - Significant mean decrease in SBP of 4.3 (95% CI: - 7.2, -1.5), 7.8 (95% CI: -10.7, -4.9), and 11.9 (95% CI: -14.9, -9.1) mmHg for placebo, user-driven, and expert-driven groups, respectively ($p = <0.01$) - No significant difference in DBP between the groups.
Santo et al. (Australia, 2018)	Parallel RCT (6 months)	CAD (average of 60 years; IG (n = 338), CG (n = 351))	IG: TEXT-ME text messaging intervention (four texts per week) + standard care vs. CG: standard care alone Characteristics: personalization, educational	*Diet* Adherence to ≥ 4 dietary recommendations (primary outcome) Adherence to 8 individual dietary guideline recommendations	*Diet* Self-assessed using the WHO STEPS instrument (13 questions about FV, fish, oil and fat, and salt intake) and a TEXT ME diet questionnaire (10 questions about FV, fish, and oil and fat consumption; where food is prepared; and salt intake) at baseline and month 6	*Diet* - Compared to the control group, participants in the intervention group had greater adherence to ≥ 4 dietary recommendations (93% vs.75%, $p < 0.001$) - Compared to the control group, participants in the intervention group had greater adherence to eating recommended levels of vegetables, fruits, fish, sodium, and takeout meals per week ($p < 0.001$)
Steinberg et al. (United States, 2020)	Parallel RCT (3 months)	HTN (Women, 21 to 70 years with a BMI > 18.5; IG (n = 30), PG (n = 29))	IG: Nutritionix diet tracking mobile app with daily feedback via text messages vs. PG: Nutritionix diet-tracking mobile app alone (no daily feedback)	*Diet* DASH diet *Other* SBP, DBP	*Diet* Automated self-administered 24-hour recall tool (ASA24) used to measure nutrient intake used at two timepoints (1 weekday, 1 weekend day). ASA24 data were used to calculate a DASH index score (ranges from 0 to 9,	*Diet* - No between group differences in the changes to the DASH scores - Both study groups had significantly higher scores after using the app interventions over a 3-month period.

Author(s) (Country, Year)	Study Design (Intervention Duration)	Population Diagnosis (age; Sample Size)	Intervention(s) vs. Comparator(s)	Outcomes Measured	Outcome Measurement	Results
			Characteristics: personalization, feedback, tracking, educational		higher number = higher adherence) *Other* Automated BP monitor	*Other* - No significant between-group change - Significant decrease in SBP of 2.7 mmHg (95% CI 0.4-5.0) in the intervention group (p = 0.03) per unit of DASH score increase. No change in DBP.
Dorsch et al. (United States, 2020)	Parallel RCT (8 weeks)	HTN (> 18 years; IG (n = 24), CG (n = 26))	IG: LowSalt4Life mobile application (provides low-sodium options while shopping or eating out) vs. CG: No app with advice to limit sodium intake to < 2400 mg/day Characteristics: personalization, feedback, educational	*Diet* Sodium intake *Other* SBP, DBP	*Diet* Spot urine with Kawasaki equation (primary outcome), Block FFQ (110-items), 24-hr urinary sodium excretion (gold standard, single measure) and automated self-administered 24-hour diet recall (single measure) administered pre and post intervention *Other* Automated blood pressure monitor used by participants who were trained to take at home measurements biweekly	*Diet* - Spot urine: Significant between group differences in sodium intake across the intervention (4026 ± 1514 to 3564 ±1121 mg/day) and control (3798 ± 1463 to 4201 ± 1594 mg/day) (p = 0.03) groups - Block FFQ: Significant between group differences in sodium intake across the intervention (3995 ± 2119 to 2441 ± 1132 mg/day) and control (3660 ± 1314 to 3156 ± 1147 mg/day) (p = 0.02) groups - 24-hr urinary sodium excretion and 24-hr dietary recall: No significant between group differences in sodium intake *Other* - No significant between group differences in SBP
Abu-El-Noor et al. (Palestine, 2021)	Parallel RCT (3 months)	HTN (> 18 years; IG (n = 97), CG (n = 94))	IG: Mobile application that educated on lifestyle changes related to hypertension with daily reminders vs.	*Diet* Low-sodium diet	The Hill- Bone compliance to high blood pressure therapy scale (15 items) which asks about the frequency of self-care behaviours of which 4 items relate to low sodium diet intake (Likert scale from	*Diet* - Compared to the control group, the intervention group had greater adherence at the end of the study period (8.36 vs. 9.65, p = 0.001)

Author(s) (Country, Year)	Study Design (Intervention Duration)	Population Diagnosis (age; Sample Size)	Intervention(s) vs. Comparator(s)	Outcomes Measured	Outcome Measurement	Results
			CG: No intervention Characteristics: personalization, educational		1 to 4 [min score of 15 to max score of 60] → lower score = higher adherence) was administered pre and post intervention	Significantly improved adherence scores in both the intervention group by -2.63 (p = 0.000), and control group by -1.25 (p = 0.000)
Bozorgi et al. (Iran, 2021)	Parallel RCT (24 weeks)	HTN (30 to 60 years; IG (n = 58), CG (n = 60))	IG: Mobile application (used at least every three days) with routine care vs. CG: Routine care Characteristics: personalization, feedback, tracking, educational	*Diet* DASH diet components combined with low-sodium and low-fat diets *Other* MAP	*Diet* Researcher-made questionnaire with 68 questions of which 5 items were related to DASH diet components and 3 related to sodium intake (diet related questions taken from the Stepwise approach to surveillance of noncommunicable diseases (STEPS) Questionnaire and Hill-Bone compliance scale), administered by trained researcher administered at baseline, week 8, and week 24 *Other* In-clinic calibration at baseline of WELCH ALLYN Tycos Jewel Movement Sphygmomanometer for at-home measures at baseline, week 8, and week 24	*Diet* - Significant increase in adherence to a low sodium diet by 1.5 (95% CI 1.2 – 1.9) in the intervention group vs. the control group - Significant increase in adherence to a low-fat diet by 1.7 (95% CI 1.3 – 2.1) in the intervention group vs. the control group. - No between group comparisons for consumption of DASH diet components *Other* Significant mean decrease in MAP by 3.4 mmHg (95% CI 1.6 – 5.2) in the intervention group compared to the control group
Studies that conducted single group pre/post analyses only						
Russaw (United States, 2014)	Pre/post design, uncontrolled (1 month)	HTN (African American women, 18 to 99 years; IG 1 (n = 46), IG 2 (n = 45))	IG 1: Loss-framed (messages which state how nonadherence to interventions harm health) vs. IG 2: Gain-framed (messages which state the benefits of adherence to interventions) text messages	*Diet* Low-sodium diet	*Diet* Hypertension self-care activity level effects (H-SCALE) (31 items total,12 items on a low-sodium diet; scale from 1 to 7 days that the participant follows recommendation → higher score = higher compliance) administered pre and post intervention	*Diet* - No between group differences assessed - There was a significant increase in scores related to a low sodium diet from 4.74 to 5.67 (p = 0.000) in the gain-framed text message group - There was a significant increase in scores related to a low sodium diet from 4.61 pre-intervention

Author(s) (Country, Year)	Study Design (Intervention Duration)	Population Diagnosis (age; Sample Size)	Intervention(s) vs. Comparator(s)	Outcomes Measured	Outcome Measurement	Results
			sent every two days Characteristics: educational			to 5.48 post-intervention (p = 0.000) in the loss-framed text message group
Nundy et al. (United States, 2013)	Pre/post design, uncontrolled (30 days)	HF (> 18 years; IG (n = 27))	IG: Educational text messages sent daily about medication, diet and appointment adherence, and HF symptoms and treatments Characteristics: personalization, educational	*Diet* Low-sodium diet, fluid intake	*Diet* Self-care Heart Failure Index (SCHFI) (contains 2 items on a low sodium diet and 1 item on the likelihood of reducing fluid intake, Scale from 1 to 4 → higher score = higher compliance) administered pre and post intervention	*Diet* - Mean score for a low sodium diet increased significantly from 2.4 $\pm$ 0.27 pre-intervention to 3.7 $\pm$ 0.21 post-intervention (p = 0.03) - No change in participants' likelihood to reduce fluid intake
Staffileno et al. (United States, 2018)	Parallel randomized trial (12 weeks)	Prehypertension (African American women, 18 to 45 years; IG 1 (n = 14), IG 2 (n = 12))	IG 1: Website-based mHealth intervention with DASH diet education modules (one per week) vs. IG 2: physical activity modules (one per week) Characteristics: personalization, feedback, tracking, educational	*Diet* DASH diet *Other* SBP, DBP	*Diet* Score measured on a researcher-generated 6-item DASH diet screener (scale from 0 to 1 with 1 indicating consumption of recommended servings of FV, low-fat dairy, whole grains, sweets, and lean meats, fish, or poultry) administered at weeks 2, 6, and 12 *Other* In-clinic measure using an automated BP cuff (average of 3 measures at baseline, week 1, and week 12)	*Diet* - In participants who received the DASH diet intervention, there was a significant increase in the DASH score from 1.5 $\pm$ 0.5 to 2.9 $\pm$ 1.1 from week 2 to week 12 (p = 0.001) - DASH scores were not assessed nor calculated for the physical activity intervention group *Other* - No change in SBP or DBP
Chen et al. (China, 2018)	Pre/post design, uncontrolled (12 weeks)	CAD (> 18 years; IG (n = 177))	IG: TAKEmeds mobile app (sent four to five messages per week about recommended lifestyle changes for CAD) Characteristics: educational	*Diet* FV	*Diet* 6-item questionnaire based on the 2011 CDC Behavioural Risk Factor Surveillance System administered at baseline and week 12	*Diet* - Significant increase in frequency of vegetable intake from 2.4 times/day at baseline to 2.7 times/day post-intervention (p = 0.01) - No change in fruit intake - 76.3% of participants found the intervention helpful for improving diet

Author(s) (Country, Year)	Study Design (Intervention Duration)	Population Diagnosis (age; Sample Size)	Intervention(s) vs. Comparator(s)	Outcomes Measured	Outcome Measurement	Results
Golshahi et al. (Iran, 2015)	Parallel RCT (8 months)	HTN (>18 years; IG 1 (n = 45), IG 2 (n = 45), IG 3 (n = 45), CG 4 (n = 45))	IG 1: Hypertension education using in-person counselling (eight one-hour sessions) vs. IG 2: four pamphlets vs. IG 3: eight text messages vs. CG: routine care Characteristics: educational	*Diet* Vegetable intake, high sodium intake (>1500 mg) *Other* SBP, DBP	*Diet* Questionnaire with items related to socioeconomic status, demographic characteristics, lifestyle behaviours, and medical history (no information indicating the type of questionnaire), administered by trained cardiology resident pre and post intervention *Other* In-clinic measures. No information regarding if measurement was performed by a clinician or automated cuff.	*Diet* - No significant change in vegetable intake (0.78 $\pm$ 0.4 to 0.84 $\pm$ 0.3 times/day, p = 0.08) in IG 3 - No change in the proportion of participants with high sodium intake (26.7% before and after the intervention, p = 0.99) in IG 3 *Other* - Significant change in SBP from 149.6 $\pm$ 3.8 (baseline) to 148.5 $\pm$ 4.9 mmHg (p = 0.02). No change in DBP.

RCT: Randomized controlled trial; IG: Intervention group; CG: Control group; PG: Placebo group; SMS: Short message service; SBP: systolic blood pressure; DBP: diastolic blood pressure; CAD: coronary artery disease; FV: fruit and vegetable consumption; HTN: Hypertension; HF: Heart failure

5.3 Secondary Outcomes

Only one clinical outcome of interest, blood pressure, was measured and this was included in six of the studies (Table 2); indices of morbidity and mortality were not measured in any of the included studies. Five of these studies measured SBP and DBP and one measured MAP (n = 1). Three of the studies showed that improvements in dietary adherence, due to the mHealth interventions, correlated with a statistically significant decrease in SBP (Liu et al., 2018; Steinberg et al., 2020) and MAP (Bozorgi et al., 2021). Another study reported an improvement in SBP, but no improvement in DBP, however, there was no improvement in dietary adherence from using the mHealth intervention, so it is unclear what led to this change (Golshahi et al., 2015). The final two studies reported no improvements in SBP or DBP (Dorsch et al., 2020; Staffileno et al., 2018).

5.4 Quality of Evidence

5.4.1 Risk of Bias

Most of the studies included in this review had a high risk of bias: Ten studies had high RoB, two studies had some concerns for RoB, and one study had low RoB (Table 4). Most studies received a rating of high RoB due to the measurement of the outcome (n = 9); others had high RoB due to confounding (n = 3), missing outcome data (n = 1), and deviations from the intended intervention (n = 1). The reasons for a RoB assessment of "some concerns" were the measurement of the outcome (n = 1), but also due to multiple measurements of the outcome being taken and only reporting results that were most statistically significant (n = 1). The study with low RoB showed significant improvements in dietary adherence between the intervention and control group among females only after the use of a web-based mHealth intervention (Liu et al., 2020). In contrast, among the studies with some concerns for RoB (n = 2), no significant between group differences in dietary adherence were reported (Liu et al., 2018; Steinberg et al., 2020). Among the studies with high RoB (n = 10), nine reported significant improvements in dietary adherence, however, only five used between group measures (Abu-El-Noor et al., 2021; Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Dorsch et al., 2020; Santo et al., 2018) and four used a pre/post analysis (Chen et al., 2018; Nundy et al., 2013; Russaw, 2014; Staffileno et al., 2018). The final study that had high RoB reported no significant differences in dietary adherence pre/post (Golshahi et al., 2015).

5.4.2 Outcome Assessment Tools

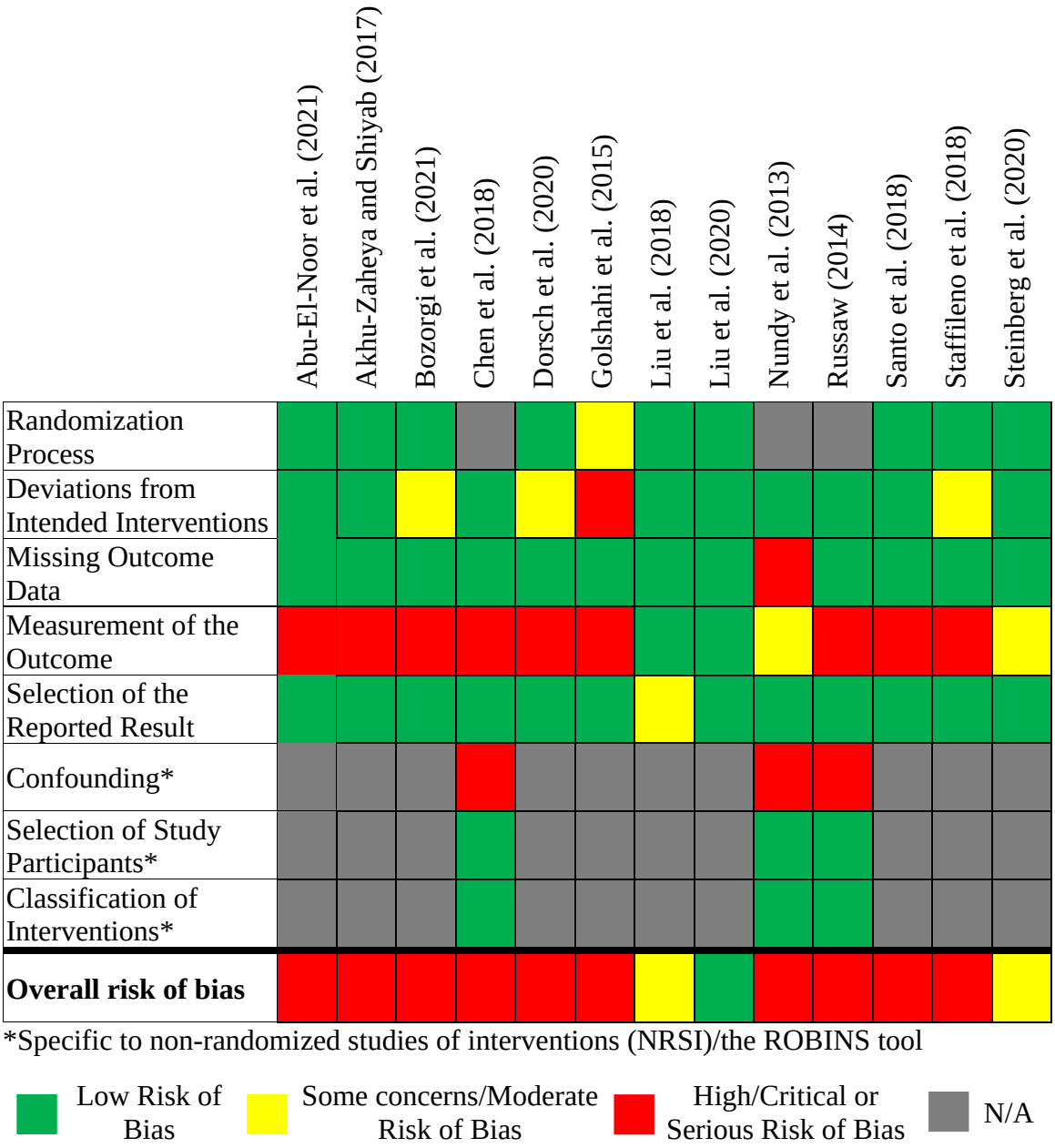
A high risk of bias was most common when measuring the dietary adherence outcome of interest, as observed in 9 of the 13 studies (Table 4). Only four studies used a dietary assessment tool based on biomarkers or participants' reporting their food and

beverage intakes, such as FFQ (NIH/NCI Diet History Questionnaire, Block FFQ), the Automated Self-Administered 24-hour (ASA24), and 24-hour urine collections or spot urine collections; some of which were insufficient in assessing the nutrient of interest (Dorsch et al., 2020; Liu et al., 2018; Liu et al., 2020; Steinberg et al., 2020). One study also used the Mediterranean Diet Adherence Screener (MEDAS) which is valid for measuring Mediterranean diet adherence behaviours (Martinez-Gonzalez et al., 2012). Tools used measure dietary outcomes did not always provide valid measures of the nutrient of interest (Appendix B). Four studies used questionnaires which measured consumption of particular foods or dietary behaviours, often using selected closed-ended question on food consumption or behaviours, but did not assess dietary intake directly (e.g., WHO stepwise approach to surveillance of noncommunicable diseases (STEPS), Hill-Bone compliance to high blood pressure therapy scale, Self-care Heart Failure Index (SCHFI), and Hypertension Self-Care Activity Level Effects (H-SCALE)). The remaining studies (n = 4) measured dietary behaviours using investigator-generated screeners and questionnaires.

It was unclear if measurement error impacted observed dietary adherence. The two studies with low risk of bias in relation to the outcome assessment showed mixed results for improvements in dietary adherence (Liu et al., 2018; Liu et al., 2020). The two studies that had some concerns for risk of bias in this area showed statistically significant improvements in dietary adherence (Nundy et al., 2013; Steinberg et al., 2020). In contrast, there were variable results among studies that had high risk of bias due to the measurement of the outcome with six showing positive results (Abu-El-Noor et al., 2021; Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Russaw, 2014; Santo et al., 2018;

Staffileno et al., 2018), two showing mixed results (Chen et al., 2018; Dorsch et al., 2020), and one showing no improvements in dietary adherence after the use of an mHealth intervention (Golshahi et al., 2015).

Table 5. *Risk of bias assessments for each bias domain for each included study based on the Cochrane risk of bias tools (Appendix B).*



5.4.3 GRADE Assessment

The evidence related to the effects of mHealth on dietary adherence was very low quality based on the GRADE framework (Table 4). The evidence started at low quality due to the inclusion of non-randomized studies and was downgraded due to several factors. Areas of particular concern, which downgraded the evidence by one level each, were the high risk of bias among ten of the thirteen included studies and the heterogeneity among the included studies. The high risk of bias in the measurement of the outcomes in nine of the thirteen studies had the greatest impact on the evidence quality. The most heterogeneity was identified among the populations (9/13 studies focused on hypertension, 1/13 on pre-hypertension, 1/13 on heart failure, and 2/13 on coronary artery disease) and intervention delivery modes (5/13 studies used text messages, 4/13 used mobile apps, 1/13 used a combination of texts and a mobile app, 2/13 used a website, and 1/13 used email). These factors greatly impacted the ability to identify the true effect of mHealth interventions on dietary adherence.

Table 4. *Summary of findings on the quality of evidence based on the GRADE framework.*

Outcome	**Number of Studies**	**Certainty of Evidence (GRADE)**	**Comments**
Dietary Adherence	10 RCTs and 3 pre-post studies	⨁◯◯◯ **Very Low**	Heterogeneity among populations and intervention delivery modes High risk of bias for the measurement of the outcome used by 9/13 studies

5.4.4 Meta-Analysis

A meta-analysis was not performed due to the heterogeneity and risk of bias identified among the included studies. As demonstrated above, there was high clinical and methodological heterogeneity based on the populations, intervention delivery modes and features, and outcome measurements. Further, most studies (10/13) had high risk of bias of which most was attributed to the measurement of the outcome in nine of the thirteen studies. Considering these factors, a meta-analysis is contraindicated.

Chapter VI: Discussion and Conclusion

Several trends were identified among the included studies. Most (10/13) of the included studies used text messages (5/13), mobile applications (4/13), or a combination of the two (1/13). The text messages and mobile applications incorporated interactive features, were personalized, and were used frequently (i.e., one or more times per week) over a short duration (i.e., one to six months). This research further demonstrates that mHealth interventions may be more effective at promoting adherence to dietary patterns rather than single dietary components such as sodium, fruits, and vegetables. mHealth interventions did not appear to differ in effectiveness, depending on whether they focused on multiple health behaviours at once, or solely on dietary behaviours. In general, although the effects of mHealth interventions were generally positive, the types of features offered by the intervention, the types of dietary recommendations included, and the duration and intensity of the interventions may have impacted their magnitude of impact.

Importantly, these results may have been impacted by the quality of the dietary assessment tools used to measure dietary adherence, a methodological feature that increased the risk of bias in many of the studies. This study also showed a lot of variation among dietary measures since studies used objective and/or subjective measures which produced different outputs such as urinary sodium or frequency of food consumption. Further, there were no apparent trends among the results in relation to the methodological quality of the dietary assessment tool used. This factor should still be considered when interpreting the results of the studies included in this systematic review, along with other methodological considerations (e.g., confounding, between group or pre/post analysis, or

the use of usual care as a comparator), which highlighted the need for higher quality research on the effects of mHealth interventions on dietary adherence for patients with CVD.

Most studies (11/13) included in this systematic review delivered the intervention for a short period of one to six months and used mHealth interventions frequently (i.e., one or more times per week). These studies showed the most statistically significant improvements in dietary adherence compared to studies that were conducted over eight or twelve months and used mHealth interventions monthly (n = 2). However, there was a lack of long-term data and information on the intensity of use needed to support dietary changes since only two of the included studies were longer than six months. These findings are supported by other systematic reviews. Park et al. (2016) also showed that mHealth interventions such as text messages and mobile applications were most effective for improving CVD outcomes (e.g., quality of life and BP) when used more than twice per week over an average of five months. Additionally, Holtz and Lauckner (2012) investigated adherence to self-management behaviours (e.g., exercise and healthy eating) among patients with diabetes and found that mHealth interventions were effective over an average of about six months. A meta-analysis on smoking found that mHealth interventions resulted in participants being about 1.7 times more likely to adhere to smoking cessation than participants with no intervention after an average of six months (Whittaker et al., 2016). This trend may be because long-term behaviour change has been shown to be difficult as described by the Strength Model of Self Control. The Strength Model of Self Control states that, when self-regulating one's behaviour, initial goals are easier to meet than subsequent goals (Webb et al., 2010). In other words, in the short-

term stages of dietary behaviour change, patients may be motivated and make efforts to change their eating behaviors based on goals set by mHealth interventions; however, over time they may be unable to meet these goals due to depleting levels of self-control. Thus, it is important that mHealth interventions have features that enable patients to regain their self-control so they can experience the benefits of dietary adherence long-term and features that also focus on consistent short-term, attainable goals.

The ability of the mHealth interventions in the articles included in this systematic review to produce statistically significant changes in dietary adherence may have also been impacted by delivery modes and features. Interventions delivered via text messages and mobile applications, or a combination of the two, appeared to have the greatest impact for improving dietary adherence when compared to other studies in this review. A meta-analysis of RCTs investigating the effects of mHealth interventions on health behaviours in healthy adults found that the use of text messages to deliver health behaviour educational messages was most effective at promoting behaviour changes (e.g., smoking cessation, physical activity, weight loss) when personalized prompts were used, compared to interventions that did not use personalization (Head et al., 2013). Another systematic review by Park et al. (2016) also found that text messages and mobile applications aiming to improve CVD risk factors and outcomes (e.g., BP and weight) were most beneficial when delivery modes were personalized and combined with each other. These text and mobile application based mHealth interventions are potentially more impactful due to the personalized and feedback-based features they offer, which can be used to engage the user throughout the day. Seven of the eight studies which had significant between group or pre/post differences in dietary adherence used

personalization and feedback to engage patients in the studies examined in this systematic review. In contrast, four of the five remaining studies used mHealth interventions which may not have been as effective (i.e., showing no significant difference in dietary adherence or only supporting adherence to some dietary components or within a certain population) due to only providing general educational information, that often lacked interactive features (Chen et al., 2018; Golshahi et al., 2015; Liu et al., 2018; Liu et al., 2020).

Active mHealth interventions that intervene to facilitate specific behaviour changes in chronic disease management are supported by behaviour change theories. This may explain why these interventions appear to have a greater impact than passive tools which only share general educational information. Furthermore, dietary adherence was improved more substantially in studies that used mHealth interventions with features such as providing feedback on behaviour, ways to self-monitor behaviour (e.g., diet tracking), prompts, reinforcement, and education, which were most often delivered through text messages and mobile applications. These features that text messages and mobile applications use can be classified under the Control Theory which states that self-management behaviours are modified when one has an ideal standard to compare their behaviours to, in a repetitive fashion (Abraham & Michie, 2008; Michie et al., 2009). In other words, if text messages and mobile applications can provide feedback based on input from patients self-monitoring their behaviour, this may allow for more effective health behaviour change since they can compare their behaviours with the healthy standards set for them by the mHealth intervention. A systematic review by Michie et al. (2009) also found that interventions that use self-monitoring and other Control Theory

techniques (e.g., goal setting, providing feedback) are significantly more effective for improving healthy eating behaviours. These findings suggest that future research that focuses on the development of mHealth interventions for health behaviour change should integrate features that are based on behaviour change theories to improve effectiveness. The literature further shows that these features may be delivered best through text messages and mobile applications.

In this study, the nutrition content included within the mHealth interventions impacted dietary adherence among patients with CVD. Of the included studies, all of the studies which used mHealth interventions that incorporated dietary patterns (e.g., the DASH diet, or the Mediterranean diet) showed statistically significant improvements in dietary adherence either between groups (n = 3) or pre/post intervention (n = 2) (Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Santo et al., 2018; Staffileno et al., 2018; Steinberg et al., 2020). Studies that used mHealth interventions which focused on individual dietary components (e.g., fruits, vegetables, or sodium) either did not show significant changes in dietary adherence pre/post intervention (Golshahi et al., 2015) or only showed improvement in adherence to some dietary components or in a specific sub-population (Dorsch et al., 2020; Liu et al., 2018; Liu et al., 2020). This finding could be due to dietary patterns having more general recommendations that emphasize the types and proportions of food consumed, such as increasing intake of fruits and vegetables, whole grains, and fish while limiting sugars, and red meats (Pearson et al., 2021; Van Horn et al., 2016). However, following recommendations for a specific dietary component, requires the patient to know how to limit sodium intake to a specific amount per day (e.g., <1500 mg/day) or consume a specific number of servings of fruits and

vegetables per day as recommended in the studies by Dorsch et al. (2020), Golshahi et al. (2015), Liu et al. (2018), and Liu et al. (2020). Following this latter recommendation requires greater food literacy, high self-efficacy and skills to be able to prepare their meals from scratch so they know the exact amount of specific dietary components they are consuming (Colatruglio & Slater, 2014). In particular, nutritional knowledge and skills to choose healthier foods at the point of purchase requires an understanding of how to read and interpret food labels, especially because processed foods are marketed by emphasizing added healthy nutrients while ignoring the other components making it more difficult to differentiate them from healthy foods (Colatruglio & Slater, 2014). Previous literature has indicated that a lack of knowledge about diet and CVD as well as a lack of self-efficacy, which are components of the TPB, are significant barriers to dietary adherence (Leon et al., 2015; McDermott et al., 2015). A qualitative study demonstrated the need for nutritional knowledge and high self-efficacy in patients with heart failure as they indicated that they required detailed information on how to prepare meals and make food choices due to their unfamiliarity with sodium levels in the food supply and not being capable of following sodium intake recommendations (Bentley et al., 2005). mHealth interventions may need to prioritize improving food literacy by providing information about how to prepare healthy meals and avoid processed foods that appear healthy to improve dietary adherence to specific dietary components.

6.1 Future Directions

This study identified several opportunities for future research on the impact of mHealth interventions on dietary adherence in CVD management. This study found that most research was conducted over a six-month period, or less. Although many of these

studies showed promising results, future studies should investigate the effect of these mHealth interventions on long-term dietary adherence to obtain a better understanding of the interventions' potential. In this systematic review, 77% of identified articles focused on patients with pre-hypertension or hypertension, with few that included patients with advanced forms of CVD. Patients with CAD and HF are more vulnerable and may experience the greatest benefit from dietary adherence in relation to their clinical outcomes. While these populations tend to be older, an increasing number of older adults have mobile devices (Navabi et al., 2016). Overall, larger trials are needed which address the limitations of the studies presented in this review with a focus on reducing risk of bias.

This systematic review also identified a need to conduct research with higher methodological quality. While 77% of studies identified were RCT designs, this study found that 77% of studies had an overall high risk of bias. Key methodological elements that must be improved in future research are the outcome measurement tools used to ascertain dietary intake and adherence, controlling for confounding, and using appropriate comparators for between group analysis so stronger conclusions can be made; pre/post analyses do not provide an accurate representation of the effect of an intervention. This study also found that many measurement tools used to evaluate dietary adherence were not appropriate for the outcome of interest. For example, FFQs and spot urine collections were used as the primary measure sodium intake (Dorsch et al., 2020), however, FFQs and spot urine collections do not give an accurate representation of sodium intake compared to food recalls or 24-hour urinary measures (Campbell et al., 2019; McLean et al., 2017). Other measures that were used included behaviour adherence

questionnaires which contained questions related to dietary adherence but did not provide actual measures of food and nutrient intake such as what was provided in studies that used 24-hour urinary excretion measures. These types of questions are particularly prone to error in self-reporting, in addition to social desirability bias. In uncontrolled studies, confounding factors should also be considered to improve study quality since there are many factors that can impact dietary adherence among patients with CVDs, such as socioeconomic status which were not accounted for in all the included studies (Ling et al., 2020). Higher quality studies are needed to guide healthcare professionals (e.g., physicians, nurses, and dietitians) on whether mHealth interventions are an appropriate self-management tool to recommend to patients with pre-hypertension, HTN, CAD, and HF. Further, core outcomes that need to be measured when studying the effectiveness of mHealth on dietary adherence need to be identified to reduce heterogeneity and be able to make meaningful comparisons.

Potentially beneficial features of mHealth interventions were ones that provided meaningful guidance to the participant. The mHealth interventions investigated in this study suggested that future efforts should go into developing mHealth interventions that guide patients with reminders (Abu-El-Noor et al., 2021; Akhu-Zaheya & Shiyab, 2017; Bozorgi et al., 2021; Nundy et al., 2013), information about how to follow dietary guidelines (Santo et al., 2018; Steinberg et al., 2020), and information about how the recommended health behaviour changes will impact their health (Russaw, 2014; Staffileno et al., 2018). It would also be beneficial to conduct comparative effectiveness trials to ascertain which delivery modes and features are most effective and impactful. For example, since text messages and mobile applications were found to be most

effective in this study, a study that compares the effectiveness of these interventions may be beneficial to determine which is best for improving dietary adherence among patients with CVD. In general, future mHealth interventions should focus on increasing food literacy in order to effectively improve dietary adherence; this can be accomplished by improving nutritional knowledge and self-efficacy among patients with CVDs (Colatruglio & Slater, 2014). The development of effective mHealth interventions has the potential to support clinical settings by introducing self-management to patients with CVDs with which the main modifiable risk factor is diet.

6.2 Strengths and Limitations

This systematic review examined mHealth interventions for dietary behaviour change, which are relatively new health monitoring and information dissemination tools that are widely accessible and relevant in today's society; particularly for addressing dietary adherence, which is a significant clinical and public health challenge. This study was strengthened with the inclusion of a medical librarian, which enhanced the quality of our search and reduced the risk of missing relevant literature. This study also included multiple reviewers at each stage of article screening and in conducting the risk of bias assessments; all of which limited the bias in the results. A potential limitation of this study is that no literature was excluded based on quality. However, we included all articles published on this topic since this is an emerging research area with a relatively limited number of studies available on this topic. The Cochrane tools were used to assess the risk of bias. These tools are quite stringent, requiring the overall risk of bias rating to be the same as the lowest rating obtained in any of the domains. This means that if just one domain has a high risk of bias, that is the overall rating, even if all other sections

obtain a rating of low risk of bias. However, it was acceptable to use these tools given that the Cochrane risk of bias tools are widely used and considered the gold standard since they address all sources of bias in RCTs and non-randomized studies (Phillips et al., 2021). This further highlights the importance of assessing individual risk of bias domains and signaling questions, to elucidate specific areas of high and low risk of bias. This study was limited by the fact that we did not conduct a meta-analysis. However, there was high clinical and methodological heterogeneity among the relatively small number of identified studies in relation to the study designs used, widely differing interventions (e.g., delivery modes and features), populations included, and modality of how primary outcome was assessed amongst studies. Therefore, since these factors made comparing studies and making conclusions more challenging, a meta-analysis was not performed.

6.3 Conclusions

In this systematic review, mHealth interventions had a primarily positive effect on dietary adherence among patients with CVD. However, due to most of the studies having a high risk of bias, caution is advised when applying these findings to clinical settings for patients with CVD. These findings highlight the need for more research of higher methodological quality in this area, in particular dietary assessment methodologies; and include research that is of longer duration and in populations with more advanced forms of CVD. High-quality research to create and evaluate mHealth interventions will support patients in dietary self-management and their health care providers in effectively delivering care, potentially decreasing the morbidity and mortality and healthcare costs associated with these conditions.

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Appendices

Appendix A. Search strategy used to identify articles for screening.

#	Searches
1	exp Cardiovascular Disease/
2	Heart Rehabilitation/
3	(“Cardiovascular Disease*” or Cardiomyopath* or “Coronary artery disease*” or “Coronary atherosclerosis” or “Coronary arteriosclerosis” or “Coronary artery disease*” or “Heart attack” or “Heart failure” or “High blood pressure” or Hypertension or Hypertensive or “Ischemic heart disease*” or “Left main disease*” or “Myocardial infarct*” or “Myocardial ischemia” or Pre-hypertension or Prehypertension or Pre-hypertensive or Prehypertensive or “Cardiac rehab*”).ti,ab.
4	1 or 2 or 3
5	exp Diet Therapy/
6	exp Food Intake/
7	exp Feeding Behavior/
8	(Diet or diets or dietary or “nutrition* therapy” or “nutrition* recommendation*” or “eating habit*” or “eating behavi*”).ti,ab.
9	(intake adj3 (food or nutrient* or nutrition* or caloric or calorie*)).ti,ab.
10	((“sodium restrict*” or “low-salt” or “salt-free” or “mediterranean” or “DASH” or “low-carbohydrate” or “low-fat” or “high-fiber” or “high-fibre”) adj2 diet*).ti,ab.
11	(fruit or fruits* or vegetable*).ti,ab.
12	or/5-11
13	Mobile phone/ or smartphone/

14	(“cell* phone*” or “cell* telephone*” or iPhone* or “mobile phone*” or “mobile telephone*” or smartphone* or “smart phone*”).ti,ab.
15	Personal digital assistant/ or Tablet computer/
16	(“handheld computer*” or “mobile device*” or “mobile electronic device*” or “mobile technology” or “Mobile technologies” or “portable electronic device*” or “digital notebook*” or “digital notepad*” or pda or “personal digital assistant*” or “pocket pc” or “tablet computer*” or “Android tablet” or ipad or ipads or “microsoft surface” or “Windows tablet”).ti,ab.
17	exp Mobile Application/
18	(mobile adj2 (app or apps or application* or software)).ti,ab.
19	(mobile adj3 website*).ti,ab.
20	WIRELESS COMMUNICATION/ or (“mobile information technolog*” or “Portable software app*” or “portable electronic app*” or bluetooth).ti,ab.
21	Telemedicine/ or Web-Based Intervention/
22	(mHealth or “m-health” or “mobile health” or “mobile phone-based support” or “digital health” or “eHealth OR e-health “).ti,ab.
23	e-mail/
24	(e-mail* or “email*”).ti,ab.
25	Text Messaging/
26	(“text messag*” or texting or texted or SMS or “short messag* service” or “multimedia messag*” or mms or “multi-media messag*”).ti,ab. Not (“SMS 201 995” or “self-management support”).mp.
27	(exp Social Media/ or blogging/ or (tweets or tweeting or blog or blogging or blogger or “social media” or “online social network*” or “Baidu Tieba” or Douban or Facebook or Foursquare or “Google app*” or Influenster or Instagram or Kuaishou or Lasso or Linkedin or Messenger or Meetup or Mocospace or Snapchat or “snap chat” or Pinterest or Qzone or “Sina Weibo” or

	Skype or Steemit or “Tencent QQ” or Tik Tok or Tiktok or Tumblr or Twitter or YouTube or “You Tube” or Reddit or Vero or Viber or SMS or Vkontakte or Wattpad or Wechat or WhatsApp or Xanga or XING).ti.) not (“SMS 201 995” or “Snyder Robinson Syndrome” or “vero cell*” or (messenger adj3 RNA)).mp.
28	or/13-27
29	4 and 12 and 28

Appendix B. Risk of bias assessments for each included study.

The following are based on the Cochrane risk of bias assessment tools for randomized (Sterne et al., 2019) and non-randomized trials (Sterne, Hernán, et al., 2016).

List of Abbreviations in Risk of Bias Assessment Tables

ANCOVA	analysis of covariance
ANOVA	analysis of variance
ASA24	automated self-administered 24-hour dietary assessment tool
BMI	body mass index
BP	blood pressure
CHBPTS	compliance to high blood pressure therapy scale
CI	confidence interval
CVD	cardiovascular disease
DASH	dietary approaches to stop hypertension
DHQ	diet history questionnaire
FFQ	food frequency questionnaire
FV	fruits and vegetables
ITT	intention to treat
MAP	mean arterial pressure
MEDAS	Mediterranean adherence screener
N	no
NCI	National Cancer Institute
NI	no information
NIH	National Institutes of Health
PA	physical activity
PN	potentially no
PY	potentially yes
REDCap	research electronic data capture

RoB 2	Revised Cochrane risk-of-bias tool for randomized trials
ROBINS-I	Risk of bias in non-randomized studies of interventions
SCHFI	self-care heart failure index
STEPS	Stepwise approach to surveillance of noncommunicable diseases
WHO	World Health Organization
Y	yes

Table 1. *Risk of bias assessment for the study by Liu et al. (2020).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	**Comments**	**Response options**
1.1 Was the allocation sequence random?	- Participants were randomly assigned using a computer randomization software. - The study was double blind, but there was no indication of allocation sequence concealment.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- No statistically significant baseline differences were found.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	**Comments**	**Response options**
2.1. Were participants aware of their assigned intervention during the trial?	- This study was double-blinded. - The intervention was delivered online and only the research coordinator was aware of the randomization code.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / PN / N / NI

2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- Linear Mixed Models with random effects intercept/post-hoc contrast (Bonferonni correction) was used for comparison of groups and confounding interactions. - Multivariable linear regression was used to ensure independent association between dietary improvement and improved CVD outcomes.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended interventions is low.	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- There was data missing for 25% of the participants randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	- Authors ensured missing data were missing at random. Multiple imputation was used to correct for bias introduced by missing data.	NA / Y / PY / PN / N

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	24-hour urinary sodium (single measure), and the NIH and the NCI Diet History Questionnaire (DHQ) were used for FV intake assessment: - Both methods are validated; the 24-hour urine collection is the gold standard assessment method for sodium. - However, while a validated way to measure sodium intake, multiple 24-hour urine collections must be administered to capture intra-individual variation and assess usual sodium intake (McLean et al., 2019).	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- The same measurement tools were used for both groups at the same time (baseline, 4 months, and 12 months).	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- This was a double-blind study.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been		NA / Y / PY / PN / N / NI

influenced by knowledge of intervention received?		
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is low.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- The published study protocol detailed the statistical analysis plan that was used in the study.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- 24-hour urinary sodium and NIH/NCI DHQ were the only measures detailed in the protocol and used to measure the outcomes of interest y. FFQs typically under-estimate sodium, so it is acceptable that 24-hour urinary sodium excretion was used.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- Appropriate analyses were used and reported.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due	Low / High / Some concerns

	to selection of the reported result is low.	

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is low with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Low" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "Low" Domain 5: Risk of bias in selection of the reported result: "Low"	(Low) / High / Some concerns

Table 2. *Risk of bias assessment for the study by Akhu-Zaheya and Shiyab (2017).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- Numbers from 1 – 180 were randomly assigned to participants by shuffling them, then the participants were assigned to each group one by one in the order of the numbers (i.e., number 1 went to the control group, 2 went to the experimental group, etc.).	(Y / PY) / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		(Y / PY) / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- The article states that there were no significant differences between study groups based on baseline characteristics except for the placebo group having significantly higher income; one difference is likely due to chance.	Y / PY / (PN / N) / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	(Low) / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- No information about blinding was provided, but there was a placebo (texts with general health advice + routine care) and control (routine care) used. - Text messages were delivered with an automated system, so carers and people delivering the interventions were unaware of participants' assigned intervention during the trial	Y / PY / (PN / N) / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / (N) / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the		(NA) / Y / PY / PN / N / NI

intended intervention that arose because of the trial context?		
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		(NA) / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		(NA) / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- ANOVA and t-tests were used to assess the effect of assignment to the intervention and participants were analyzed based on the intervention they were assigned to.	(Y / PY) / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended interventions is low.	(Low) / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	**Comments**	**Response options**
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 12% of the participants who were randomized.	Y / PY / (PN) / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	- There is no indication that missing outcome data was accounted for in the analysis.	NA / Y / PY / PN / (N)

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	- All the reasons for missing outcome data were documented and none were related to the outcome or the participants' health status. Missing data was due to reasons such as providing the wrong phone number, becoming bored with the study, frustration with the researchers, their phone being disconnected, changing numbers, or their phone being switched off for the duration of the study.	NA / Y / PY / PN / (N) / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	(Low) / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- The Mediterranean Diet Adherence Screener (MEDAS) was used which is a valid measure of Mediterranean diet adherence behaviours (Martinez-Gonzalez et al., 2012). - While this tool may be validated, it did not provide a direct measure of sodium intake using a biomarker (24-hour urine collection) or self-reported measures of total food and beverage intake over a given period (e.g., food records, food recalls) to enable an assessment of measured food and nutrient intakes.	Y / (PY) / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- Both groups had the same measurements at baseline and after 3 months.	Y / PY / PN / (N) / NI

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- There was no information provided about the blinding of outcome assessors.	NA / Y / PY / PN / N / (NI)
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- The outcome was self-reported by participants, so assessment would not be influenced by outcome assessors knowing the intervention received. Also, participants were likely unaware of the intervention they received due to the placebo group.	NA / Y / PY / PN / (N) / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is high.	Low / (High) / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- Data was analyzed based on what was reported in the methods section of the published article.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Only the MEDAS measurement tool was used and reported.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- Only ANOVA and t-tests were performed for their respective measures.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to selection of the reported results is low.	Low / High / Some concerns

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Low" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns

Table 3. *Risk of bias assessment for the study by Liu et al. (2018).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- A web-based program was used for randomization (www.randomize.net) with randomly permuted blocks. - Allocation of participants was concealed from investigators and research assistants.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- Table 1 shows an even distribution of baseline characteristics (age, gender, ethnicity, etc.) between groups.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- The study was double-blinded from baseline to 4-month follow-up.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / PN / N / NI

2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- A two-tailed test was used to compare differences in the mean scores between the groups (p-values and 95%CI were reported).	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended intervention is low.	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 10% of the participants who were randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- The NIH/NCI DHQ was used to assess dietary intake, specifically FV intake. This is a validated tool for the measurement of FV (Thompson et al., 2002).	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- Measurements for all intervention groups were made with the NIH/NCI DHQ at baseline and after 4 months.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- Outcome assessors remained blinded for the duration of the study.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is low.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- Only the NIH/NCI DHQ was reported in the protocol and used in the analysis. - No statistical analysis plan was stated in the protocol.	Y / PY / PN / N / (NI)
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Only the NIH/NCI DHQ was used to measure vegetable and fruit intake.	Y / PY / PN / (N) / NI
5.3 ... multiple eligible analyses of the data?	- Only results from statistical analysis reported in the methods section were used.	Y / PY / (PN) / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for risk of bias in selection of the reported results.	Low / High / (Some concerns)

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for the overall risk of bias with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Low" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "Low"	Low / High / (Some concerns)

	Domain 5: Risk of bias in selection of the reported result: “Some concerns”	

Table 4. *Risk of bias assessment for the study by Steinberg et al. (2020).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	**Comments**	**Response options**
1.1 Was the allocation sequence random?	- A biostatistician created an allocation table using Sealed Envelope then uploaded it to Research Electronic Data Capture (REDCap) which conducted random assignment. Randomization included a permuted block design with block sizes of 4 to 8. - Allocation was revealed to unblinded research staff upon random assignment by the REDCap software, allowing the research staff to orient the participant to either the DASH Cloud intervention or an active comparator arm.	(Y) / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		(Y) / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- Baseline measures were taken for each participant, but no statistical comparisons between groups were reported.	Y / PY / PN / N / (NI)
Risk-of-bias judgement	As per the “Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)” (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	(Low) / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	**Comments**	**Response options**
2.1. Were participants aware of their assigned		(Y) / PY / PN / N / NI

intervention during the trial?	- Due to the nature of the intervention, blinding of participants was not possible. - The people delivering the interventions were not blinded.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	- No deviations from the intended intervention were reported.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- Linear regression models were used to control for baseline levels of dietary adherence. - Repeated measures analysis of variance was used to measure within-group changes.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended interventions is low.	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 27% of the participants who were randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	- Sensitivity analysis models were used to compare invalid/missing data to those included in analysis.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- Automated self-administered 24-hour (ASA24) recall tool was used, which is a valid measure of nutrient intake (Kirkpatrick et al., 2014). Two measures were captured (1 weekend day, 1 weekday) which captures intra-individual variation in intake. Results from ASA24 were compared to recommended intake of DASH components to determine adherence to the DASH diet.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed	- The outcome was measured in the same way in both study groups.	Y / PY / PN / N / NI

between intervention groups?		
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- The outcome assessors were not blinded.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- Since participants were aware of the intervention they received, there is a risk of social desirability bias, and they may have over or underreported their food/nutrient intakes.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for risk of bias due to the measurement of the outcome.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- The statistical analysis was consistent with the methods described in the article.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Only the ASA24 data was used.	Y / PY / PN / N / NI

5.3 ... multiple eligible analyses of the data?	- Only one analysis was used to assess the outcome.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to selection of the reported results is low.	Low / High / Some concerns

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for overall risk of bias with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Low" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "Some concerns" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns

Table 5. *Risk of bias assessment for the study by Santo et al. (2018).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- One to one block randomization (block size of 8) was performed with a computerised randomization software. - Study personnel were blinded to intervention assignment. Randomization was concealed using password protection until the end of the study.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- Baseline measures were mostly similar for the intervention and control groups (between group comparisons not performed for baseline characteristics). - The original baseline characteristics were created by Chow et al. (2015)	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- Participants received a text informing them of their assigned intervention. - Delivery of text messages was fully automated, therefore only participants were aware of intervention assignment (single-blind study). - Participants were asked to not reveal their assigned group to study personnel and clinicians.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI

2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / PN / N / (NI)
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		(NA) / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		(NA) / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- Between group differences over time were assessed.	(Y / PY) / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended interventions is low.	(Low) / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	**Comments**	**Response options**
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 8% of the participants who were randomized.	(Y / PY) / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		(NA) / Y / PY / PN / N

3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- A 10-item self-report questionnaire ((WHO) STEPS) and TEXT ME diet questionnaire were used (assesses general dietary behaviours). No information is available on the validation of these measurement tools but appear to ask relevant questions for the outcome of interest. Importantly, the tools it did not provide a direct measure of intake using a biomarker (e.g., 24-hour urine collection) or self-reported measures of total food and beverage intake over a given period (e.g., food records, food recalls) to enable an assessment of food and nutrient intakes consumed.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- Both groups had the same measurements done at baseline and after 6 months.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- Participants were aware of their intervention status, and they assessed the outcome given it was a self-report measure.	NA / Y / PY / PN / N / NI

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- There is potential for social desirability bias and recall bias since participants were aware of their intervention and reported their own dietary habits for an entire week all at once. Bias could have been due to knowledge of the intervention, but the assessment questions are prone to bias and/or error on their own.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is high.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- The analysis methods were detailed in the methods section of the article and protocol (Chow et al., 2015).	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Only the WHO STEPS and TEXT ME questionnaires, which are complementary to each other, were reported and described in the methods.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- Only one analysis was conducted (logistical regression), as described in the methods.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due	Low / High / Some concerns

	to selection of the reported result is low**.**	

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Low" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns

Table 6. *Risk of bias assessment for the study by Russaw (2014).*

Signalling questions	Description	Response options
Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study? **If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signaling questions need be considered	- There are more participants with pre-hypertension in the gain-framed text group compared to loss-framed text group and more participants with normal blood pressure in the loss-framed text group compared to the grain-framed text group.	Y / PY / PN / N
If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, go to question 1.3.	- There were no switches between intervention groups.	NA / Y / PY / PN / N / NI
1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)		NA / Y / PY / PN / N / NI

Questions relating to baseline confounding only		
1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	- All potential confounding variables were not measured (e.g., comorbidities, socio-demographic variables) and thus were not controlled for. - There was no sub-group analysis performed.	NA / Y / PY / PN / N / NI
1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	- There was no controlling for post-intervention confounding variables.	NA / Y / PY / PN / N / NI
Questions relating to baseline and time-varying confounding		
1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding?		NA / Y / PY / PN / N / NI
1.8. **If Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to confounding is serious.	Low / Moderate / Serious / Critical / NI

Bias in selection of participants into the study		
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? **If N/PN to 2.1:** go to 2.4 2.2. **If Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention? 2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?	- Any differences between participant groups were identified before the start of the intervention with pre-specified inclusion and exclusion criteria.	Y / PY / PN / N / NI NA / Y / PY / PN / N / NI NA / Y / PY / PN / N / NI
2.4. Do start of follow-up and start of intervention coincide for most participants?	- All participants began the intervention and follow-up at the same time (follow-up was after one month of the intervention for all participants).	Y / PY / PN / N / NI
2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to selection of participants is low.	Low / Moderate / Serious / Critical / NI

Bias in classification of interventions		
3.1 Were intervention groups clearly defined?	- Each intervention group received loss- or gain-framed texts every two days for one month.	Y / PY / PN / N / NI
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	- The intervention was defined by the delivery of pre-defined automated texts.	Y / PY / PN / N / NI
3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	- Random assignment to each intervention group occurred indicating that classification of the intervention status was not affected by knowledge of the outcome or risk of outcome.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to classification of interventions is low.	Low / Moderate / Serious / Critical / NI

Bias due to deviations from intended interventions		
If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2		
4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	- All participants remained in the intended intervention group as the intervention was automated and participants were unable to switch on their own.	Y / PY / PN / N / NI
4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?		NA / Y / PY / PN / N / NI
If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
4.3. Were important co-interventions balanced across intervention groups?		Y / PY / PN / N / NI

4.4. Was the intervention implemented successfully for most participants?		Y / PY / PN / N / NI
4.5. Did study participants adhere to the assigned intervention regimen?		Y / PY / PN / N / NI
4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to deviations from the intended intervention is low.	Low / Moderate / Serious / Critical / NI

Bias due to missing data		
5.1 Were outcome data available for all, or nearly all, participants?	- Data was missing for 7% of the participants who were randomized.	Y / PY / PN / N / NI
5.2 Were participants excluded due to missing data on intervention status?	- The intervention status was clear for all participants.	Y / PY / PN / N / NI
5.3 Were participants excluded due to missing data on other variables needed for the analysis?	- No participants were excluded from the analysis because of missing information regarding confounders.	Y / PY / PN / N / NI
5.4 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions?		NA / Y / PY / PN / N / NI
5.5 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool"	Low / Moderate / Serious / Critical / NI

	(Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to missing data is low.	

Bias in measurement of outcomes		
6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	- Underreporting is possible with self-assessed measures of hypertension self-care activities, such as low sodium dietary practices, due to social desirability bias.	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of the intervention received by study participants?	- Participants were the outcome assessors and were aware of their intervention status.	Y / PY / PN / N / NI
6.3 Were the methods of outcome assessment comparable across intervention groups?	- The H-Scale was used for all participants in both intervention groups.	Y / PY / PN / N / NI
6.4 Were any systematic errors in measurement of the outcome related to intervention received?	- While this tool may be validated, it did not provide a direct measure of sodium intake using a biomarker (24-hour urine collection) or self-reported measures of total food and beverage intake over a given period (e.g., food records, food recalls) to enable an assessment of measured food and nutrient intakes.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to measurement of outcomes is serious.	Low / Moderate / Serious / Critical / NI

Bias in selection of the reported result		
Is the reported effect estimate likely to be selected, on the basis of the results, from...	- Only one measurement of low-sodium diet was used (H-Scale).	

7.1. ... multiple outcome *measurements* within the outcome domain?		Y / PY / PN / N / NI
7.2 ... multiple *analyses* of the intervention-outcome relationship?	- Only one analysis was performed to analyze the data (t-tests).	Y / PY / PN / N / NI
7.3 ... different *subgroups*?	- No subgroup analyses were conducted; therefore, the effect estimates could not have been selected based on results from a subgroup analysis.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to selection of the reported result is low.	Low / Moderate / Serious / Critical / NI

Overall bias		
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the overall risk of bias is serious with the following results in each domain: Domain 1: Bias due to confounding: "Serious" Domain 2: Bias in selection of participants into the study: "Low" Domain 3: Bias in classification of interventions: "Low" Domain 4: Bias due to deviations from intended interventions: "Low" Domain 5: Bias due to missing data: "Low" Domain 6: Bias in measurement of the outcome: "Critical" Domain 7: Bias in selection of the reported result: "Low"	Low / Moderate / Serious / Critical / NI

Table 7. *Risk of bias assessment for the study by Nundy et al. (2013).*

Signalling questions	Description	Response options
Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study? **If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered	- Baseline measures were a potential confounding factor (93% of participants were African American, unequal number of males (60%) and females (40%), phone usage (80% always carry their phone and 66% were very comfortable using text messaging)).	(Y) / PY / PN / N
If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, go to question 1.3.	- There was only one intervention group in this study.	NA / Y / PY / PN / (N) / NI
1.3. Were intervention discontinuations		(NA) / Y / PY / PN / N / NI

or switches likely to be related to factors that are prognostic for the outcome? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)		

Questions relating to baseline confounding only		
1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	- Only a paired t-test and Wilcoxon ranked sum test were performed which do not control for baseline confounding factors.	NA / Y / PY / PN / N / NI
1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	- There was no controlling for post-intervention variables that could have been affected by the intervention.	NA / Y / PY / PN / N / NI
Questions relating to baseline and time-varying confounding		
1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and		NA / Y / PY / PN / N / NI

for time-varying confounding?		
1.8. **If Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to confounding is serious.	Low / Moderate / Serious / Critical / NI

Bias in selection of participants into the study		
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? **If N/PN to 2.1:** go to 2.4	- Inclusion criteria were defined before participants started the intervention.	Y / PY / PN / N / NI
2.2. **If Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention?		NA / Y / PY / PN / N / NI
2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?		NA / Y / PY / PN / N / NI
2.4. Do start of follow-up and start of intervention coincide for most participants?	- All participants began receiving texts after hospital discharge.	Y / PY / PN / N / NI
2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases?		NA / Y / PY / PN / N / NI

Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to selection of participants is low.	Low / Moderate / Serious / Critical / NI

Bias in classification of interventions		
3.1 Were intervention groups clearly defined?	- There was one intervention group that was clearly described, including examples of texts provided.	Y / PY / PN / N / NI
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	- There was only one intervention group which was established before the participants began the study.	Y / PY / PN / N / NI
3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	- All the participants received the same intervention.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to classification of interventions is low.	Low / Moderate / Serious / Critical / NI

Bias due to deviations from intended interventions		
If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2		
4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	- There was only one group, so there is no reason for cross-over, but it is unclear if any other type of deviation occurred.	Y / PY / PN / (N) / NI
4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?		(NA) / Y / PY / PN / N / NI
If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
4.3. Were important co-interventions balanced across intervention groups?		Y / PY / PN / N / NI
4.4. Was the intervention implemented successfully for most participants?		Y / PY / PN / N / NI
4.5. Did study participants adhere to the assigned intervention regimen?		Y / PY / PN / N / NI
4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to deviations from the intended intervention is low.	(Low) / Moderate / Serious / Critical / NI

Bias due to missing data		
5.1 Were outcome data available for all, or nearly all, participants?	- Data was missing for 60% of the participants (2 died, 1 admitted to subacute facility, 4 had technology issues).	Y / PY / PN / (N) / NI

5.2 Were participants excluded due to missing data on intervention status?	- No data was excluded for participants with missing information regarding intervention status or confounders.	Y / PY / PN / N / NI
5.3 Were participants excluded due to missing data on other variables needed for the analysis?	- Participants were excluded if they were lost to follow-up, not due to missing data.	Y / PY / PN / N / NI
5.4 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions?	- Only one intervention group was involved in the study.	NA / Y / PY / PN / N / NI
5.5 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data?	- Sensitivity analyses were not conducted.	NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to missing data is critical.	Low / Moderate / Serious / Critical / NI

Bias in measurement of outcomes		
6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	- A self-assessed measure was used, so underreporting and errors of sodium intake are a possibility due to social desirability bias.	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of the intervention received by study participants?	- All of the participants received the intervention and assessors delivered a survey about satisfaction with using the text message intervention, so they were aware of the nature of the intervention.	Y / PY / PN / N / NI
6.3 Were the methods of outcome assessment	- There was only one intervention group.	Y / PY / PN / N / NI

comparable across intervention groups?		
6.4 Were any systematic errors in measurement of the outcome related to intervention received?	- The outcome was measured with a validated self-report index that contains questions related to sodium and fluid. - While this tool may be validated, it did not provide a direct measure of sodium intake using a biomarker (24-hour urine collection) or self-reported measures of total food and beverage intake over a given period (e.g., food records, food recalls) to enable an assessment of measured food and nutrient intakes.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to measurement of outcomes is moderate.	Low / Moderate / Serious / Critical / NI

Bias in selection of the reported result		
Is the reported effect estimate likely to be selected, on the basis of the results, from... 7.1. ... multiple outcome *measurements* within the outcome domain?	- Only one measurement was used to assess the outcomes of interest (SCHFI).	Y / PY / PN / N / NI
7.2 ... multiple *analyses* of the intervention-outcome relationship?	- Only one analysis performed on the outcomes of interest (paired t-test).	Y / PY / PN / N / NI
7.3 ... different *subgroups*?	- No subgroups were analyzed.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of	Low / Moderate / Serious / Critical / NI

	bias due to selection of the reported result is low	

Overall bias		
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the overall risk of bias is critical with the following results in each domain: Domain 1: Bias due to confounding: "Serious" Domain 2: Bias in selection of participants into the study: "Low" Domain 3: Bias in classification of interventions: "Low" Domain 4: Bias due to deviations from intended interventions: "Low" Domain 5: Bias due to missing data: "Critical" Domain 6: Bias in measurement of the outcome: "Moderate" Domain 7: Bias in selection of the reported result: "Low"	Low / Moderate / Serious / (Critical) / NI

Table 8. *Risk of bias assessment for the study by Dorsch et al. (2020).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- The Internet-based University of Michigan Consulting for Statistics, Computing, and Analytics Research randomization instrument was used to allocate participants (stratified by gender).	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- Table 1 shows no significant differences in age, gender, race, ethnicity, or baseline clinical outcomes (sodium and blood pressure) between groups.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- The intervention involved use of a mobile app, so blinding was not possible. - This was stated to be an open label study.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	- The intervention was implemented as intended within the trial context (the mobile app was only utilised by participants in the intervention group).	NA / Y / PY / PN / N / NI

2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- A two-sided unpaired t-test was used to compare changes in sodium intake over time in the intervention versus control groups.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for the risk of bias due to deviations from the intended interventions.	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	**Comments**	**Response options**
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 4% of the participants who were randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI

3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	Primary outcome: - Spot urine with the Kawasaki equation was used which is not a validated way to measure sodium intake of individuals (Zhou et al., 2017). Secondary outcomes: - The 24-hr urine collection was used which is the gold standard for dietary sodium intake assessment. While a validated way to measure sodium intake, multiple measures should be taken to measure usual intake, so there may be some bias introduced (McLean et al., 2019). - The Block FFQ was used which tends to underestimate sodium intake (McLean et al., 2017). - The ASA24 was used, and evidence indicates that this 24-hour recall is an acceptable measure of sodium intake (Kirkpatrick et al., 2014).	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- All measurements were taken with the same tools and at the same time for both groups.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- This was an open label study.	NA / Y / PY / PN / N / NI

4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- Self-reported dietary intake comes with a risk of under/over-reporting due to social desireability bias, and potentially errors due to memory recall (e.g., with the ASA24). - It is unlikely that objective measures of sodium intake could have been influenced by knowledge of the intervention received.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is high.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- All dietary assessment tools and the overall statistical analysis plan were pre-specified in the protocol.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Although multiple measurements were made, all the results were reported, and all were measured at the same time point.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- All eligible reported results correspond to the intended analyses.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to selection of the reported result is low.	Low / High / Some concerns

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Some concerns" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns

Table 9. *Risk of bias assessment for the study by Abu-El-Noor et al. (2021).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- The study indicates that participants were randomly assigned to each group but gives no indication how. - No blinding method was listed, however, there is no reason participants would have known allocation before receiving the intervention.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- Table 2 shows that there are no significant differences between the baseline characteristics of the groups.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias from the randomization process is low.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- Due to the intervention (mobile app) that was used, blinding was likely not possible. - The intervention used automated reminders and educational messages sent through an app, Thus the people delivering the interventions were not aware of participants' assigned intervention. However, participants were recruited at primary healthcare centres indicating that their carers may have been aware of the	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI

	intervention, impacting non-protocol interventions.	
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	- No changes in intervention occurred due to trial context (reasons for incomplete intervention were incorrect phone number provided, death, not answering automated calls, or travel).	NA / Y / PY / PN / (N) / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		(NA) / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		(NA) / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- ANOVA, t-test, and chi-squared test were used to analyze differences between the control and intervention groups. Participants with missing outcome data were excluded from the analysis (modified ITT).	(Y / PY) / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended interventions is low.	(Low) / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 12% of the participants who were randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	- Authors stated no significant difference in adherence scores between groups for different socioeconomic characteristics at baseline. This indicates that, if missing data caused an uneven distribution of socioeconomic characteristics between the intervention and control groups, the results should not have been biased.	NA / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- A validated measure was used to measure dietary adherence to a reduced sodium diet (Hill-Bone CHBPTS) (Kim et al., 2000). While this tool may be validated, it did not provide a direct measure of sodium intake using a biomarker (24-hour urine collection) or self-reported measures of total food and beverage	Y / PY / PN / N / NI

	intake over a given period (e.g., food records, food recalls) to enable an assessment of measured food and nutrient intakes.	
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- The same scale was utilised for measuring dietary adherence in both groups at baseline and after 3 months.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- External data collection was performed (researchers did not conduct data collection/assess the outcomes), however, data was self-reported, and participants were aware of their intervention status.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- Participants could have overreported adherence to diet and this is likely if they believed the mobile application would be helpful.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is high.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- Reported results from the measurement tool using the analysis methods that were specified in the methods section of the article.	Y / PY / PN / N / NI

Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Only one scale was specified in the methods and analyzed in the results.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- Analyses were used based on the type of variable assessed (ANOVA, t-test, and chi-squared test).	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to selection of the reported result is low.	Low / High / Some concerns

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Low" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns

Table 10. *Risk of bias assessment for the study by Bozorgi et al. (2021).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- A random sequence was generated using online randomization in advance; permuted block randomization with a block size of four was used to randomize in a 1:1 ratio. - The allocation sequence was concealed since it was determined in advance and an online tool was used to randomize participants.	(Y) / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		(Y) / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- All baseline characteristics were fairly evenly distributed between groups (Table 2). - Some differences (unknown if they are statistically significant) in the duration of disease, MAP, PA, and adherence to a low-fat diet at baseline were observed. There is a chance that the differences are due to a small sample size.	Y / PY / (PN) / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	(Low) / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- Participants and carers were unable to be blinded given that a mobile application was used. - Due to information being reported through the app, carers and people delivering the intervention were aware of the participants' assignment.	(Y) / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned		(Y) / PY / PN / N / NI

intervention during the trial?		
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	- All participants remained with the intended intervention defined in the protocol for the duration of the study.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- Repeated measures ANCOVA and 95% CI were used to determine the difference in mean adherence score over time for both the control and intervention groups.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	- Only 2 people dropped out of the study from the intervention group.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for risk of bias from the intended interventions	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 3% of the participants randomized.	Y / PY / PN / N / NI

3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		(NA) / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		(NA) / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	- As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	(Low) / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- The STEPS questionnaire, developed by the WHO, was used to ask participants to self-report their intake and adherence to vegetables, dairy, and fruits. However, there are no questions to ascertain adherence to a low-sodium diet in the STEPS questionnaire v 1.4. - The 14-item Hill-Bone compliance scale was used which contains 3 items related to low-sodium diet adherence, but this was stated as being a measure for medication adherence only. - There were no questions in either the STEPS or Hill-Bone questionnaires to assess adherence to a low-fat diet. It is unclear which questions were used to assess adherence to a low-fat diet.	(Y) / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed	- The outcome was measured and analyzed the same for both groups.	Y / PY / PN / (N) / NI

between intervention groups?	- The outcome was measured at the same time for all participants (at baseline, the 8th week, and the 24th week).	
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- Physicians administering the questionnaires were aware of participant assignment due to measurement of usability and satisfaction with the app.	NA/ Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- Self-report questionnaires were used to measure dietary adherence which is subject to social desirability bias. - No objective measures of dietary adherence were performed.	NA/ Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the measurement of the outcome is high.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- The protocol indicated the questionnaire and the statistical methods that would be used for the analysis of dietary adherence (Ashoorkhani et al., 2016).	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		

5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- The questionnaire was predefined and reported in the final report.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- The statistical methods were clearly described in the protocol (Ashoorkhani et al., 2016).	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to selection of the reported results is low.	Low / High / Some concerns

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Some concerns" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns

Table 11. *Risk of bias assessment for the study by Staffileno et al. (2018).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- A computer-generated random numbers table was used to randomize participants. - Personnel who enrolled participants were not involved in the randomization.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- There were no significant differences in baseline characteristics (age, BP, weight, and BMI) between the intervention groups.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the randomization process is low.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- Blinding was not possible due to the nature of intervention. - The principal investigator was responsible for delivering the interventions to each group and was informed of assignment. Research assistants were also aware of participants' assigned intervention.	Y / PY / PN / N / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	- No participants appear to have deviated from the intended intervention. Participants were only given access to the educational modules that corresponded to their group.	NA / Y / PY / PN / N / NI

2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- No between group comparisons were conducted, therefore the true effect of the diet intervention cannot be determined. The Sign test was used to determine differences in total DASH score before and after the intervention. - General linear models were used to test the difference between baseline characteristics and within-group effect sizes.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	- Only one participant was excluded from analysis in the DASH diet group.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias for deviations from the intended interventions is low.	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- Data was missing for 26% of the participants randomized.	Y / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	- The article states that there was no significant difference between participants that were lost to	NA / Y / PY / PN / N

	follow-up and participants included in the analysis.	
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NA / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	Low / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- A 6-item DASH screener was used to assess daily intake of DASH diet components, but the screener was only used at week 2, 6, and 12, so recall bias is likely. Self-report questionnaires are subject to underreporting and recall and social desirability bias. The tool used also did not provide a direct measure of intake using a biomarker (e.g., 24-hour urine collection) or self-reported measures of total food and beverage intake over a given period (e.g., food records, food recalls) to enable an assessment of measured food and nutrient intakes consumed.	Y / PY / PN / N / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- The same measure of dietary adherence was used at baseline and 12 weeks for the DASH diet group, but no measure of diet was done for the physical activity group.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the	- The components of the DASH diet score were self-reported by participants (the assessors in this	NA / Y / PY / PN / N / NI

intervention received by study participants?	case) who were aware of their intervention assignment.	
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- The participants were aware of the outcome being assessed due to the measure being self-report, therefore, they may have overreported consumption of recommended servings of DASH diet components; there was likelihood of social desirability bias.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to the measurement of the outcome is high.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- The analyses conducted were concordant with the stated methods.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- Only the 6-item DASH screener was used.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- There was only one analysis conducted.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al.,	Low / High / Some concerns

	2019) algorithm, the risk of bias due to selection of the reported results is low.	

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Low" Domain 2: Risk of bias due to deviations from the intended interventions: "Some concerns" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / (High) / Some concerns

Table 12. *Risk of bias assessment for the study by Chen et al. (2018).*

Signalling questions	Description	Response options
Bias due to confounding		
1.1 Is there potential for confounding of the effect of intervention in this study? **If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered	- There was an uneven distribution of males and females (68% males).	Y / PY / PN / N
If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
1.2. Was the analysis based on splitting participants' follow up time according to intervention received? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, go to question 1.3.	- Only one intervention group was included, and it was a pre-post study design. Therefore, there was no switching between intervention groups.	NA / Y / PY / PN / N / NI
1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? **If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) **If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)		NA / Y / PY / PN / N / NI
Questions relating to baseline confounding only		
1.4. Did the authors use an appropriate analysis method that controlled for	- A regression model was used, and subgroup analysis was performed, but only for	NA / Y / PY / PN / N / NI

all the important confounding domains?	primary outcomes, not dietary adherence.	
1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	- There was no controlling for post-intervention variables.	NA / Y / PY / PN / N / NI
Questions relating to baseline and time-varying confounding		
1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding?		NA / Y / PY / PN / N / NI
1.8. **If Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to confounding is serious.	Low / Moderate / Serious / Critical / NI

Bias in selection of participants into the study		
2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? **If N/PN to 2.1:** go to 2.4	- Inclusion criteria were defined before participants started the intervention. However, it is unclear if participants were consecutively approached to participate, which may further introduce bias.	Y / PY / PN / N / NI
2.2. **If Y/PY to 2.1**: Were the post-intervention		NA / Y / PY / PN / N / NI

variables that influenced selection likely to be associated with intervention? 2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?		NA / Y / PY / PN / N / NI
2.4. Do start of follow-up and start of intervention coincide for most participants?	- All participants were followed for 12 weeks after the start of the intervention.	Y / PY / PN / N / NI
2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to selection of participants is low.	Low / Moderate / Serious / Critical / NI

Bias in classification of interventions		
3.1 Were intervention groups clearly defined?	- Texts from a bank of 60 messages were automatically sent to participants 4-5 times a week (on weekdays) for 12 weeks. Text messages included information on medications, diet, and smoking cessation in relation to heart disease.	Y / PY / PN / N / NI
3.2 Was the information used to define intervention groups recorded at the start of the intervention?	- Sixty automated messages were determined before participants started the intervention.	Y / PY / PN / N / NI
3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	- All of the participants received the same intervention.	Y / PY / PN / N / NI

Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to classification of interventions is low.	(Low) / Moderate / Serious / Critical / NI

Bias due to deviations from intended interventions		
If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2		
4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	- There is not enough information to determine if participants deviated from the intended intervention.	Y / PY / PN / N / (NI)
4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?		(NA) / Y / PY / PN / N / NI
If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
4.3. Were important co-interventions balanced across intervention groups?		Y / PY / PN / N / NI
4.4. Was the intervention implemented successfully for most participants?		Y / PY / PN / N / NI
4.5. Did study participants adhere to the assigned intervention regimen?		Y / PY / PN / N / NI
4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to deviations from the intended intervention is low.	(Low) / Moderate / Serious / Critical / NI

Bias due to missing data		
5.1 Were outcome data available for all, or nearly all, participants?	- Data was missing for 7% of the participants.	Y / PY / PN / N / NI
5.2 Were participants excluded due to missing data on intervention status?	- All participants received the same intervention.	Y / PY / PN / N / NI
5.3 Were participants excluded due to missing data on other variables needed for the analysis?	- Participants were only excluded if they were lost to follow-up.	Y / PY / PN / N / NI
5.4 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions?		NA / Y / PY / PN / N / NI
5.5 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data?		NA / Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to missing data is low.	Low / Moderate / Serious / Critical / NI

Bias in measurement of outcomes		
6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	- A self-assessed measure was used, so there may have been over-reporting and/or errors of fruit and vegetable intake due to social desirability bias.	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of the intervention received by study participants?	- All participants received the same intervention, and a survey was conducted by outcome assessors to assess satisfaction with the intervention.	Y / PY / PN / N / NI
6.3 Were the methods of outcome assessment comparable across intervention groups?	- The 6-item brief dietary assessment tool from the Behavioral Risk Factor Surveillance System fruit and	Y / PY / PN / N / NI

	vegetable dietary intake module was used for all participants.	
6.4 Were any systematic errors in measurement of the outcome related to intervention received?	- Over-reporting and error could have occurred due to self-assessed measures of FV intake. Prospective measures of total food and beverage intake (e.g., food records, food recalls) may have enabled a more valid assessment of measured food and nutrient intakes.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to measurement of outcomes is serious.	Low / Moderate / Serious / Critical / NI

Bias in selection of the reported result		
Is the reported effect estimate likely to be selected, on the basis of the results, from...		
7.1. ... multiple outcome *measurements* within the outcome domain?	- Only one measure of dietary adherence was included.	Y / PY / PN / N / NI
7.2 ... multiple *analyses* of the intervention-outcome relationship?	- Only one analysis was used to compare pre-post effects of intervention.	Y / PY / PN / N / NI
7.3 ... different *subgroups*?	- Subgroups were not reported.	Y / PY / PN / N / NI
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the risk of bias due to selection of the reported result is low.	Low / Moderate / Serious / Critical / NI

Overall bias		
Risk of bias judgement	As per the "Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool" (Sterne, Higgins, et al., 2016) guidance document, the overall risk of bias is serious with the following results in each domain: Domain 1: Bias due to confounding: "Serious" Domain 2: Bias in selection of participants into the study: "Low" Domain 3: Bias in classification of interventions: "Low" Domain 4: Bias due to deviations from intended interventions: "Low" Domain 5: Bias due to missing data: "Low" Domain 6: Bias in measurement of the outcome: "Serious" Domain 7: Bias in selection of the reported result: "Low"	Low / Moderate / Serious / Critical / NI

Table 13. *Risk of bias assessment for the study by Golshahi et al. (2015).*

Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?	- Block randomization was used. No further information about randomization was provided.	Y / PY / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y / PY / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	- Table 1 shows some characteristics (gender, and education) unevenly distributed between groups, but these differences were not statistically significant.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, there are some concerns for risk of bias due to the randomization process.	Low / High / Some concerns

Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?	- Blinding was not possible for participants or carers due to the nature of interventions (received pamphlets, texts, face-to-face	Y / PY / PN / N / NI

2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	counselling, or usual hypertension care).	Y / PY / PN / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	- A published protocol was not found. - The percentage of participants that adhered to each intervention was not reported, but all participants were followed up with.	NA / Y / PY / PN / N / NI
2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / PN / N / NI
2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / Y / PY / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	- No between and within group comparisons were conducted to indicate the effect of assignment to the comparator groups vs. control. - Wilcoxon Rank tests and paired t-tests were used to determine differences before and after the intervention period.	Y / PY / PN / N / NI
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	- It is unclear if all participants that were randomized provided data.	NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to deviations from the intended interventions is high.	Low / High / Some concerns

Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?	- All of the participants were followed up with until the end of the study.	(Y) / PY / PN / N / NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?		(NA) / Y / PY / PN / N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		(NA) / Y / PY / PN / N / NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		(NA) / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to missing outcome data is low.	(Low) / High / Some concerns

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?	- There was little information on the questionnaire and questions used to determine dietary intake outcomes. No direct measure of intake using biomarkers (24-hour urine collection) was used or self-reported measures of total food and beverage intake over a given period (e.g., food records, food recalls) to enable an assessment of measured food and nutrient intakes. Also, an interview conducted by cardiology residents, which increases risk of social desirability bias and misreporting, especially with a questionnaire asking participants to self-report their adherence.	(Y) / PY / PN / N / NI

4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	- The same questionnaire was used for all participants in all intervention groups, both baseline and 8 months.	Y / PY / PN / N / NI
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	- There is no indication that outcome assessors were blinded.	NA / Y / PY / PN / N / NI
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	- Underreporting of sodium intake and overreporting of vegetable intake may have occurred with knowledge of the intervention.	NA / Y / PY / PN / N / NI
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to measurement of the outcome is high.	Low / High / Some concerns

Domain 5: Risk of bias in selection of the reported result

Signalling questions	**Comments**	**Response options**
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	- Reported results of salt and vegetable intake matched what was described in the statistical analysis methodology of the article.	Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		

5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	- There was only one measurement used for each outcome of interest.	Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?	- There was only one analysis of the data which was appropriate.	Y / PY / PN / N / NI
Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the risk of bias due to selection of the reported result is low.	Low / High / Some concerns

Overall risk of bias

Risk-of-bias judgement	As per the "Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)" (J. P. T. Higgins et al., 2019) algorithm, the overall risk of bias is high with the following results in each domain: Domain 1: Risk of bias arising from the randomization process: "Some concerns" Domain 2: Risk of bias due to deviations from the intended interventions: "High" Domain 3: Missing outcome data: "Low" Domain 4: Risk of bias in measurement of the outcome: "High" Domain 5: Risk of bias in selection of the reported result: "Low"	Low / High / Some concerns