- 1 Are dietary interventions with a behaviour change theoretical framework effective in
- 2 changing dietary patterns? A systematic review
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15 Abstract

Background: The term 'whole dietary pattern' can be defined as the quantity, frequency, 16 variety and combination of different foods and drinks typically consumed and a growing body 17 of research supports the role of whole dietary patterns in influencing the risk of non-18 communicable diseases. For example, the 'Mediterranean diet', which compared to the typical 19 20 Western diet is rich in fruits and vegetables, whole grains, and oily fish, is associated with 21 reduced risk of cardiovascular disease and cancer. Social Cognition Models provide a basis for understanding the determinants of behaviour and are made up of behavioural constructs that 22 interventions target to change dietary behaviour. The aim of this systematic review was to 23 provide a comprehensive assessment of the effectiveness and use of psychological theory in 24 dietary interventions that promote a whole dietary pattern. 25

Methods: We undertook a systematic review using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis to synthesize quantitative research studies found in Embase, Medline, PsycInfo, CINAHL and Web of Science. The studies included were randomised and non-randomised trials published in English, involving the implementation of a whole dietary pattern using a Social Cognition Model to facilitate this. Two independent reviewers searched the articles and extracted data from the articles. The quality of the articles was evaluated using Black and Down quality checklist and Theory Coding Scheme.

33 Results: Nine intervention studies met the criteria for inclusion. Data from studies reporting 34 on individual food group scores indicated that dietary scores improved for at least one food 35 group. Overall, studies reported a moderate application of the theory coding scheme, with poor 36 reporting on fidelity.

37 Conclusion: To our knowledge, this is the first review to investigate psychological theory38 driven interventions to promote whole dietary patterns. This review found mixed results for the

effectiveness of using psychological theory to promote whole dietary pattern consumption.
However, the studies in this review scored mostly moderate on the theory coding scheme
suggesting studies are not rigorously applying theory to intervention design. Few studies
reported high on treatment fidelity, therefore, translation of research interventions into practice
may further impact on effectiveness of intervention.. Further research is needed to identify
which behaviour change theory and techniques are most salient in dietary interventions.

Key words: Psychological theory, whole dietary patterns, theory coding scheme

Major non communicable diseases (NCD) include, heart disease, stroke, cancer, 49 diabetes, and chronic respiratory disease, and are estimated to represent 41 million deaths per 50 annum globally [1]. According to the World Health Organisation (WHO, 2016) [1], a number 51 of preventable risk factors underlie many NCD's and are the leading cause of death and 52 53 disability globally regardless of economic status with one of the main risk factors considered 54 to be poor diet attributable to 11 million deaths globally in 2017 [2]. Previously, the focus of research has been on single nutrients or single food groups, as the main disease states were due 55 to nutritional deficiencies. However, the burden of disease has switched [2] to cancer, diabetes, 56 and cardiovascular disease, due to demographic and epidemiological transitions, which are now 57 the leading causes of death globally. This was partly due to a shift in the food environment, 58 with people consuming more high-carbohydrate, low fat diets, which in turn lead people to 59 60 consume more refined carbohydrates and refined sugar, which increases the risk of 61 cardiometabolic diseases [3]. The dietary determinants of diseases such as cancer and diabetes are different from those of undernutrition and nutrient deficiency states [4]. Non-62 communicable diseases have multiple interacting dietary determinants consisting of either 63 64 excess or insufficient intake, which cumulatively affect disease over time [5]. Therefore, research has gone beyond the single nutrient approach and focused on whole dietary patterns, 65 66 which may be more beneficial to health due to the synergism between nutrients and food groups [6]. 67

Improving dietary quality is not easily achieved. Healthy eating patterns revolve around regular consumption of a variety of foods from key food groups including cereal and cereal products, fruits and vegetables, meat and non-meat alternatives and dairy/non-dairy alternatives with the aim of optimizing nutrient intakes conducive to reducing the risk of chronic illness [7]. Globally between 1990-2010, consumption of healthy foods has increased, however, the consumption of unhealthy foods had increased to a greater extent [8]. As opposed to a "healthy" dietary pattern , which can be nutrient based or only focus on certain aspects of a diet, for the purpose of this review, a whole dietary pattern is defined as the quantities, proportions, variety or combination of different foods in relation to the 5 foods groups of the Eatwell Guide, UK [9] and the MyPlate, USA [10] (fruit & vegetables, carbohydrates/grains, protein, fats & sugar, dairy products), or an established healthy eating pattern such as the Mediterranean diet [11].

It is clear, that interventions to promote adherence to a healthy dietary pattern are 80 warranted. There is an array of research examining and evaluating the effectiveness of dietary 81 interventions on chronic illnesses. There is some evidence in the literature to suggest, that the 82 reporting of psychological theory use in behaviour change intervention development is 83 associated with larger intervention effects [12]. Using psychological theory to design behaviour 84 change interventions, provides a framework to accumulate evidence, test hypothesis, identify 85 86 specific constructs that may influence behaviour and suggest which behaviour change techniques should be used in behavioural interventions [13]. 87

Social Cognition Models (SCMs) (e.g. Theory of Planned Behaviour (TPB)) [14] are 88 the most commonly used theories within the field of health psychology and behaviour change 89 90 [15]. SCMs are useful for explaining, predicting, and understanding dietary behaviours, and in 91 the design of dietary interventions to promote dietary change [16]. However, while SCMs has been used to predict dietary patterns [17,18], there is less evidence in the literature examining 92 the effectiveness of interventions that use SCMs to promote whole dietary patterns, such as the 93 94 Mediterranean [11], MIND [19], and DASH [20] diets. However, reviews in the literature show mixed results for the effectiveness of theory based dietary interventions. One meta-analysis 95 96 found no association between dietary intervention effectiveness and theory use [21], while another meta-analysis on theory-based fruit and vegetable intervention among children, found 97

that after considering quality of studies, theory was associated with vegetable consumption
only[22]. Furthermore, a previous review indicated that theory-based interventions were less
effective than non-theory-based interventions [23]. However, such research is held back by
limitations in the extent to which interventions report on theory use, and insufficient
descriptions of intervention content [24].

103 Some studies have been shown not to extensively use psychological theory in developing interventions [25]. One way to examine how theory has been applied to 104 interventions is by applying the 19-item theory coding scheme (TCS) [26]. This scheme 105 specifies whether theory is mentioned, whether theoretical constructs are targeted or measured, 106 if theory was used to select recipients or to tailor the intervention and if theory was tested or 107 refined. The TCS is a reliable tool to describe theory-based interventions; to inform evidence 108 synthesis within reviews and has been used widely in systematic reviews to assess the 109 effectiveness of theory and intervention effectiveness. 110

To advance behavioural research, improvement in methodologies are needed, with 111 112 treatment fidelity proposed as a key area for improvement. Treatment fidelity refers to the processes used to ensure intervention components are delivered as intended [28]. To make valid 113 interpretations regarding the efficacy of a behavioural intervention, it is important to provide 114 details of treatment fidelity, which provides insights into the gap between theory and practice. 115 To provide this information, specification of the intervention program is required. According 116 to Bellg et al. [29], five domains to assess, monitor or enhance treatment fidelity have been 117 identified by, as part of The National Institute of Health (NIH) and Behaviour Change 118 Consortium (BCC), which are: (1) design of study, (2) training providers (3) delivery of 119 treatment (4) receipt of treatment (5) enactment of treatment skills. 120

Previous systematic reviews have assessed the effectiveness of behavioural 121 interventions on fruit and vegetable consumption [30], reduce sugar intake [31], or only 122 reporting on dietary behaviours using one SCM, such as the Social Cognitive Theory [32]. One 123 systematic review [32] aimed to identify effective dietary interventions for older people. 124 However, this review examined both whole dietary patterns and single food groups such as 125 fruit and vegetables. Furthermore, while this review reported the delivery of educational 126 127 sessions, no theory was mentioned, or theoretical constructs reported. To our knowledge, the current review is the first to assess the effectiveness of SCMs in dietary interventions that use 128 a "whole dietary pattern". Therefore, the aim of this systematic review was to provide a 129 comprehensive and systematic assessment of the effectiveness and use of SCMs in dietary 130 interventions that promote "whole dietary patterns" in adults. 131

132 **Objectives:**

133	• To describe the extent of psychological theory in the design and implementation of
134	dietary interventions to promote whole dietary patterns
135	• To evaluate the implementation of psychological theory in the design of dietary
136	interventions to promote whole dietary patterns
137	• To determine the effectiveness of psychological theory based dietary interventions
138	• To explore the extent to which the fidelity of the intervention is monitored in these
139	studies.
140	• To provide recommendations for future research to promote whole dietary patterns
141	Methods
142	The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) (see
143	supplementary data file 1) [33] was used to inform the design, conduct and reporting of this
144	systematic review. No ethical approval was sought as only secondary analysis of existing

148 Selection Criteria

In accordance with PRISMA, the PICOs (population, intervention, comparison, outcome, andstudy design) approach were used to formulate the selection criteria. (see Table 1).

Inclusion criteria: 1) study population: all adults aged 18 years or over; 2) study intervention: an intervention involving a "whole dietary pattern" such as the Mediterranean diet [11] Dash diet [18] and MIND diet [17] or foods analysed from at least 4 out of 5 of the food groups identified by the Eatwell Guide, UK (protein, grains/carbohydrates, oil and fats, dairy, fruit/vegetable; 3) psychological theory: studies were included that used a social cognition model to design their intervention (e.g. TPB); 4) study design: randomised controlled trials and , including single arm studies, and pilot studies published in English.

Exclusion criteria: 1) study population; studies targeting a population under 18 years old were 158 excluded; 2) study intervention: studies were not included where the dietary behaviour was a 159 160 de facto medical treatment e.g. gluten free diet. Also, studies analysing data from only single food group and nutrients, such as, fruit and vegetable, or omega 3 were excluded, as these do 161 not constitute a "whole dietary pattern"; 3) psychological theory: studies that do not mention 162 or report on a social cognition model were excluded; 4) study design: studies that were not 163 interventions, such as qualitative or cross-sectional studies were excluded from this review. 164 (see Table 1). 165

166 Search Strategy and Study Identification

Literature searches were conducted by (DT) between April 2019 and January 2020 using the
following databases: EMBASE (1974-2020), Medline (1974-2020), PsycInfo (1974-2020),

CINAHL (1937-1-2020) and Web of Science (1950-2020). ProQuest Dissertations & Thesis 169 was reviewed to locate unpublished studies and, reference lists of the selected studies for 170 inclusion were searched manually. The following search terms were used in different 171 combinations. Theoretical framework, behaviour change theory, Theory of Planned Behaviour, 172 Theory of Reasoned Action, Health Belief Model, Self-determination Theory, Stages of 173 Change Model, Health Action Process Approach, COM-B model, Social Cognitive Theory, 174 175 Control Theory, Self-Efficacy Theory, Social Ecological Model, healthy eating, dietary intervention, dietary patterns, healthy eating, whole diets, Mediterranean, DASH and MIND 176 177 diet were also chosen as search terms as these are "whole dietary patterns", they do not eliminate any food group and promote a healthy lifestyle [7]. The studies were screened by the 178 titles and abstracts. Studies that did not meet the inclusion criteria were excluded. Two 179 researchers (DT&ES) reviewed the abstracts independently that were ambiguous for inclusion. 180 Any disagreements were resolved through discussion with a third researcher (JM). 181

182 Data Extraction.

The following information was extracted from each study: author, design, country, quality
score, participants characteristics, intervention, control, dietary pattern, theoretical model,
outcome measures, main findings (Table 2).

186 Methodological Quality

The modified version of Downs and Blacks [34] quality checklist was used as some of the included studies were non-randomised studies. Question 27 was modified to "Did the study have sufficient power?" with one point awarded if a sample size calculation was completed [35]. Two researchers (DT&ES) independently assessed the quality of the studies. The Downs and Blacks quality checklist is considered a reliable and valid tool suitable for the use in random and non-random studies [36]. Studies were assessed on quality of reporting (10 questions; partially = 1, no = 0 or yes = 2, or yes =1, no=0), external validity (3 questions; yes = 1, no = 0,unable to determine = 0), internal validity – measurement bias (7questions; yes = 1, no = 0, unable to determine = 0), internal validity – selection bias (6 questions; yes = 1, no = 0, unable to determine = 0) and power (1 question ; yes = 1, no = 0, unable to determine = 0), equating to a total achievable score of 28 (see Table 3). Studies that scored less than 14 were considered poor, those that scored between 14-18 were considered fair, those that scored between 19-23 were considered good and those scoring between 24-28 were considered excellent [37].

In addition to study quality being formally assessed, the Theory Coding Scheme (TCS) 200 [26] was used to assess the extent to which theory was used to design behaviour change 201 interventions within each study. The TCS consists of 19 items across 6 categories relating to; 202 whether a theory was mentioned, if the relevant theoretical constructs are targeted, if theory 203 was used to select participants and/or tailor interventions and if the relevant constructs were 204 measured, if theory was tested and if theory was refined. Responses to all items with the 205 exception of item 7 and 10 with a "yes" were given 1 point and those responded with a "no" 206 and "don't know" were given 0 points. Items 7 (All intervention techniques are explicitly linked 207 to at least 1 theory-relevant construct) and 10 (All theory-relevant constructs are explicitly 208 209 linked to at least 1 intervention technique) were given 2 points if the criteria were met (see Table 4). Similar scoring has previously been applied [38]. Similar to previous research using 210 211 the TCS [39], this review scored each study as having a weak (0-7), moderate (8-15), or strong (16-23) use of theory. There was an initial 95% agreement of codes, which demonstrates an 212 acceptable level of agreement. Discussion between researchers resolved any differences within 213 the coding process. 214

215 Treatment fidelity

Treatment fidelity was assessed using a 29-item checklist [40] which mapped onto 5 domains identified by Bellg.[29] 1) treatment design (6 items); 2) treatment providers (7 items); 3) delivery of treatment (9 items); 4) receipt of treatment (5 items); enactment of treatment skills (2 items). The ability to draw solid conclusions from a study may be decreased, if any one of the domains lack consideration [40] (see Table 5).

221 **Results**

222 Study Characteristic

223 The basic characteristics of included studies are shown in Table 2.

224 Type of Studies.

Nine studies met the inclusion criteria (see Figure 1). Seven of the included studies were RCT's
[41-47] and 2 non-RCT's [48-49].

227 **Type of Participants**

In all studies, participants had a mean age ranging from 34 to 72 years. Females represented between 45-100% of the overall sample. One study [43] did not state the number of males and females who participated. Six of the included studies had apparent healthy participants [41,42,45,47-49]. Three of the included studies had participants with a clinical diagnosis [43,44,46]. Of the nine studies, one was carried out in Australia [44], four in the USA [41,45,46,47], one in Canada [48], and three in the Mediterranean (Greece, Italy and Spain)[42,43,49].

235 **Type of Dietary Pattern**

All studies included a whole dietary pattern that took into consideration the main food groups:
protein, grains/carbohydrates, oil and fats, dairy, fruit/vegetable (n=9). Two of the nine studies

specifically examined the Mediterranean diet [48,49], and one examined the DASH diet [46].

239 Type of Primary Outcome.

Outcome measures varied across studies. Two studies used the HEI-2005 to assess overall diet 240 quality and adherence to the recommended diet [42,43], with higher scores representing better 241 diet quality. One study assessed adherence to the Mediterranean diet with the Mediterranean 242 Diet Adherence Screener (MEDAS) [49], with higher scores representing higher adherence to 243 244 the Mediterranean diet. One study used the Diet Guidelines Index (DGI) to measure adherence to healthy recommendations over the previous month. A diet score is obtained with a range of 245 0-150, with higher scores representing higher levels of healthy eating [44]. One study assessed 246 dietary behaviour with a food frequency questionnaire [50] and compliance to USDA Food 247 Pyramid [41,51]. One study used the AHEI-2010 to assess diet quality [45] with a total score 248 between 0-110, with the higher score representing better diet quality. One study [48] assessed 249 the level of adherence to the Mediterranean diet with a Medscore, which was calculated based 250 on the food frequency questionnaire used in the study. Scores ranged from 0-44, with higher 251 scores representing higher adherence to the Mediterranean diet. One study captured 252 recommended foods by a 24-hour recall questionnaire and compliance with USDA Food 253 Pyramid [47,51]. Finally, one study [46] used the Willett Food frequency Questionnaire [52] to 254 derive a DASH adherence score, with a potential DASH score of 1-40 over 8 food components. 255 Each component score between 1-5, with a higher score representing higher adherence. 256

257 Quality of Studies.

Out of a total score of 28, all 9 included studies scored between 15 and 25 on the Black and Downs quality assessment checklist (see Table 3), with one study scoring 25 which is considered excellent quality [45]. Four studies scored between 19-23 which is considered good quality [41,44,47,48], and the remaining four studies scoring between 14-18 which is considered fair quality [42,43,46,49]. Overall, the 9 included studies scored high on the first

subscale of the checklist (reporting). None of the included studies met the criteria for "external 263 validity" subscale, with two studies scoring zero [42,43]. The following section is internal 264 validity-bias which studies scored relatively high on this subsection with scores between 4-6 265 out of a possible 7. The following subsection is internal validity-confounding (selection bias), 266 which yielded the most variety of scores, which may be due to having different experimental 267 designs. Only one of the RCTs [44] reported sufficiently on randomised intervention 268 269 assignment concealment. Lastly, power to detect a significant effect was reported by 4 studies [41,45,47,48]. 270

271 Impact of intervention on dietary behaviour

Two studies [48,49] examined the impact of a theory-based intervention on adherence to the 272 Mediterranean diet. Both studies calculated an overall Medscore pre-post intervention, 273 274 calculated from the Mediterranean Diet Adherence Screener (MEDAS) [49], or a food frequency questionnaire [48]. Both studies reported a significant increase in Medscore post 275 276 intervention. One study [46] examined the impact of a tailored behavioural intervention (TBI) on adherence to the DASH diet, compared to a non-tailored intervention (NTI) and usual care 277 (UC) group. At 6 months follow-up, TBI had a higher DASH score than UC and NTI. However, 278 for individual components of the DASH diet such as fruit and vegetables, and wholegrains, 279 there was no significant difference between groups on scores at 6-month follow-up. The 280 281 remaining 6 studies examined individual components of dietary behaviours based on AHEI [45], HEI [42,43] DGI [44], FFQ [41] and 24hr recall/MyPyramid [47]. From theses 6 studies, 282 one study reported no improvement in dietary behaviour [44]. Only one study reported a 283 significant improvement in fruit [45], vegetable intake [43], carbohydrates/grains [42] and dairy 284 [42]. Two studies reported improvements in protein (fish, poultry, beans, meat, or eggs) [45,47] 285 286 and total fats [41,42].

287 Extent of theory use

The extent to which theory was used within the selected studies was assessed using the TCS 288 (Table 4) [26]. From the 9 included studies, the mean total TCS score across studies was 11, 289 which is a moderate application of theory. One study [42] showed a weak application of theory, 290 seven studies [41,43-45,47-49] were moderate, and one study showed a strong application of 291 292 theory [46]. These scores suggest that theory had not been extensively applied to the design, implementation, and evaluation of behaviour change interventions, and/or theory use was 293 reported with insufficient detail. These scores suggest that most studies are not explicitly 294 reporting theory use in sufficient detail and/or fail to rigorously apply theory to intervention 295 design and implementation. The following section describes the use of theory within the 296 selected studies in terms of the 6 categories of coded items of the TCS [26]: (1) mention of 297 theory; (2) targeting of theoretical constructs;(3) using theory to select recipients or tailor 298 interventions; (4), measurement of constructs; (5) testing of mediation effects; (6) and refining 299 300 theory.

301 *Category 1: Mention of theory (Items 1-3)*

All studies (N=9) mentioned a theory (item 1, Table 4), with only 6 studies referring to theory as a predictor of behaviour and provided evidence of the association of the theory or theoretical construct and target behaviour. For example, one study using the Health Belief Model [41] stated that the best predictor of nutrition related behaviour change is the benefit-cost ratio, and for a change in nutrition behaviour to occur, the perceived benefits must outweigh the barriers. Out of the 9 studies, 7 were reported to be a single theory (item 3, Table 4) such as HAPA, SDT and TTM, while 2 studies combined theories (HBM and SCT).

309 *Category 2: Are relevant constructs targeted (Item 5, 7-11)*

Eight of the studies used theory or predictors to select/develop intervention techniques (Item 310 5, Table 4). Regarding linking intervention techniques to theoretical constructs, only 4 studies 311 explicitly linked all intervention techniques to at least one theoretical construct (Item 7, Table 312 4), with a further 5 studies linking at least one, but not all, intervention techniques to at least 313 one theoretical construct (Item 8, Table 4). Three studies linked a group of techniques to a 314 group of constructs (Item 9, Table 4). Only 4 studies explicitly linked all relevant theoretical 315 316 constructs to at least one intervention technique (Item 10, Table 4), with a further 4 studies linking at least one, but not all, constructs with at least one technique (Item 11, Table 4). For 317 318 example, one study [41] used the HBM to develop an educational intervention to improve dietary practices for CVD prevention. However, the intervention focused on perceived benefits 319 and barriers and neglected other key concepts such as susceptibility and severity of illness, 320 health motivation and perceived control. Another study [47] used the SCT model to develop a 321 dietary intervention and focused their intervention techniques on self-regulation techniques, 322 such as self-monitoring and goal setting, neglecting concepts such as outcome expectancy. 323 Therefore, more than half (N=5) of these studies did not utilise the full predictive power of 324 their chosen theory. 325

326 *Category 3: Is theory to select participants or tailor interventions.*

None of the included studies used theory to select participants (Item 4, Table 4), and only 1
study tailored intervention techniques to the participants. Therefore, the intervention differed
for subgroups of participants that varied for a particular construct at baseline (Item 6, Table 4).
This study was based on the TTM, and the intervention delivered to each participant varied
depending on their stage of change at baseline.

332 Category 4: Are relevant constructs measured

Seven of the studies reported measuring theoretical constructs pre-post intervention (Item 12,
Table 4), and reporting on the validity and reliability of the scales used to measure
constructs/predictors (Item 13, Table 4).

336 *Category 5: Testing theory*

Seven of the studies reported randomisation, two studies were non-RCTs (Item 14, Table 4). 337 Four of the studies interventions changed the target theoretical constructs. For example, one 338 study [41] using the HBM significantly increased perceived benefits of adoption of positive 339 340 dietary behaviours and increased nutrition knowledge of CVD and cancer. Also, another study [45] reported that HAPA outcomes in the intervention group reported significantly greater 341 frequency of action planning, and action and coping self-efficacy at follow-up (Item 15, Table 342 343 4). Seven of the studies discussed the results in relation to theory (Item 16, Table 4) and three 344 provided support for theory (Item 17, Table 4). That is, studies reported that constructs within the theory, significantly mediated the relationship between the intervention and outcomes. For 345 example, one study [48] that used self-determination theory found that eating related self-346 determined motivation was associated with an increased adherence to the Mediterranean diet. 347

348 *Category 6: Refining theory*

Refining of theory, or suggestions for future refinement was not reported by any of the includedstudies (Item 18, Table 4).

351 Fidelity of interventions

Of the 9 included studies, two studies included an assessment on all 5 domains [45,48]. One study included an assessment on only one domain [49]. Two studies included an assessment on two domains [41,42]. Three studies included an assessment on three domains [43,44,46]. One study included an assessment on four domains [47] (see Table 5). 356 *Study design*

All studies made an assessment on study design [41-49], with information about treatment dose provided in the intervention condition, and two providing information on treatment dose in the comparison group [45,47]. All studies reported underpinning theory [41-49]. No further trained providers were employed to allow for setbacks.

361 *Training providers*

Two studies provided information on training providers [45,48]. These studies provided information on how trainers were trained and standardisation of provider training. Strategies to enhance training providers included, using the same provider throughout the intervention [48], use of certified trainers [48], and train all providers together [45].

366 *Delivery of treatment*

Eight of the studies made at least one assessment on the delivery of treatment [41-48], which was assessed through direct observation of the intervention. Making sure that the interventions were delivered, and the appropriate dose given, being the most reported item in this domain.

Various criteria were used to evaluate the treatment delivery. For example, one study [47] used a checklist after each session to measure degree of adherence, and class attendance [42,47]. In another study, participants reported on the acceptability of the intervention [44], and how the participants rated the overall delivery of the intervention [48]. Other strategies used to assess delivery of treatment were the use of manuals to aid delivery [41,44-46].

375 *Receipt of treatment*

376 Six studies made at least one assessment on the receipt of treatment. Various strategies were 377 used to assess receipt between authors and included ensuring that participants understood the 378 intervention [43-48] and providing resources to enable participants to perform the behaviour [47,48]. Other strategies to assess receipt of treatment included reviewing self-monitoring data
[43,45], and assessing confidence in behavioural skills [44-47].

381 Enactment of treatment skills

Observation and practice of skills required within interventions were included in three of the studies. Observation of these skills in daily life were carried out in two of the studies [47,49]. Other strategies to assess whether treatment was being enacted were daily self-monitoring and tracking devices [45].

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387 Discussion

To our knowledge, this is the first systematic review to assess the effectiveness of 388 dietary interventions promoting a whole dietary pattern using a social cognition model. This 389 systematic review has investigated the extent of SCM use in designing interventions to increase 390 adherence to whole dietary patterns and explored the associations between theory use and 391 intervention effectiveness. This review also explored the extent to which the 5 domains of 392 treatment fidelity are reported in the selected studies. We found that the overall scores, across 393 the 9 included studies, measured by the TCS averaged 10 out of a possible 21 points. This 394 suggests that the studies were not explicitly theoretically informed or used to their full extent, 395 396 even though theory was explicitly mentioned. This review also found that only two studies made at least one assessment on all five fidelity domains. As all five components of fidelity 397 are mutually exclusive. The validity of a study is potentially compromised with inattention to 398 any one of the 5 fidelity domains [40]. 399

400 Five behaviour change theories were used in the studies of the current review (HAPA,
401 HBM, SCT, SDT, TTM), with HAPA used by 3 of the 9 included studies. Out of the 9 studies,

one study [44] showed no improvements in diet following the intervention based on the Diet 402 Guidelines Index (DGI) to create an overall single score of diet quality. Previous research has 403 404 stated that the way in which dietary scales score individual food groups to create a single score can be problematic [53], as observed associations could be due to single components rather 405 than the overall dietary pattern [7]. Small-scale scores are less informative, as the extremes and 406 the inherent characteristics of a pattern or a behaviour may not be fully captured [7]. 407 408 Furthermore, research has shown that participants had better control of their diet and ate more healthily compared to the general population and therefore, changes in diet quality could not 409 410 be detected [44]. Also, those in the intervention group perceived less risk awareness to those in the control group, which could have affected their engagement in the intervention [44]. 411 Awareness of the importance of balanced nutrition is shown to be an important factor that may 412 influence dietary choices [54,55]. 413

414 Five of the studies used a dietary scale that reported individual food group scores. All 415 five studies improved dietary scores for at least one food group. One study found a significant improvement in fruit intake [45], vegetable intake [43], carbohydrates/grains [42], and dairy 416 [42]. Two studies reported improvements in protein (fish, poultry, beans, meat, or eggs) 417 [45,47], and total fats [41,42]. These findings are consistent with a previous review which 418 found that out of half the studies examined, at least one aspect of diet had not improved, with 419 a further 5 studies showing no improvement in diet quality. However, in the same review, one 420 quarter of the studies were found to be explicitly theoretically informed (based on the Theory 421 Coding Scheme), and significantly improved diet quality. Of these 10 studies, 8 reported 422 improvements in fruit and vegetables [25] suggesting that interventions that use behaviour 423 change theory rigorously, lead to better outcomes in trials. 424

The current review found limited association between the use of psychological theoryand improved intervention outcomes, with only three of the studies in this review reporting an

association between theory and intervention effectiveness (assessed through individual TCS 427 items). One possible explanation for the relatively limited effectiveness of the interventions 428 reviewed in the present review is that they apply theory insufficiently. The current review 429 showed that the included studies revealed theoretical implementation weaknesses. Most 430 notably, linking all BCTs to theoretical constructs were met by only 4 out of the 9 studies. 431 Compared to previous findings [56,57], this review observed a closer link between intervention 432 433 and theory, measured by a higher percentage of studies reporting on linkage between theoretical constructs and intervention techniques (TCS items 7-11). However, in the current 434 435 review, only studies that explicitly mentioned theory were included. Previous research targeted interventions whether theory was mentioned or not for the target behaviour, with only half the 436 studies reported to be explicitly based on theory, and of those, few targeted all theoretical 437 constructs or linked all BCTs to theoretical constructs [57]. 438

Theory based interventions can help us understand processes and effectiveness of 439 440 interventions [26] by identifying key constructs that are shown to be related to behaviour and behaviour change techniques related to the relevant constructs, that can be used as a target for 441 intervention design. Research has found that interventions tailored on theoretical concepts 442 were more effective than those tailored on behaviour alone [58]. However, as more than half 443 of the included studies in the current review did not report on this concept fully, the findings 444 limit the extent of evidence of behaviour change factors [59]. Overall, these finding highlight 445 the need for clearer selection, application, and reporting of theory use in the design, 446 implementation, and evaluation of dietary intervention. 447

Linking BCT's to theory provides an opportunity to refine theory [26] and while the current review found that most of the studies linked at least one BCT to theoretical constructs, none of the studies used the results to refine theory. It is important to address this, as not only is theory important in the developmental stages of intervention design and future interventions,

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but to the advancement of our understanding of how interventions affect behaviour. This lack
of refining theory from interventions is common, with similar results found in recent research
[59-61].

A second explanation to the relatively limited effectiveness of the interventions 455 reviewed in the present review is that the interventions may not have been delivered as the 456 457 designers intended. This cannot be ruled out, as treatment fidelity was poorly reported in the current review studies. According to Borrelli. [40] there are five domains of treatment fidelity: 458 study design, training, delivery, receipt, and enactment, all of which are mutually exclusive. 459 The validity of a study is potentially compromised with inattention to any one of the 5 fidelity 460 domains. The overall reporting of treatment fidelity in the current review is poor, with only 3 461 studies reporting on more than three of the five domains. This finding is similar to other reviews 462 considering fidelity [40,62]. Overall, we found that regardless of the theory coding scheme 463 score, those studies that reported high on fidelity, reported improvements in more food groups 464 465 than those with lower fidelity. For example, one study [46] that scored the highest in the theory coding scheme but low on fidelity, reported a significant improvement in overall DASH score, 466 but not in any of the individual food groups. Furthermore, two of the included studies that 467 scored relatively low on the theory coding scheme and high on fidelity, reported better 468 adherence to the Mediterranean diet [48], and improvement to several of the food groups 469 470 including fruit, red meat, processed meat and total AHEI scores [45]. Moreover, two studies scoring the lowest on fidelity [41,42], reported improvements on less food groups, which did 471 not include fruit or vegetables. However, these two studies also scored relatively low on the 472 TCS. This finding demonstrates that, while the TCS addresses fidelity of treatment such as, 473 explicitly identifying and use of theory as a basis for intervention design, there are other factors 474 that are not addressed. For example, if insignificant results were found in an intervention and 475 only one or two of the domains were of high fidelity, it is possible that the insignificant results 476

were due to a lack of attention in the other domains [28], such as the training providers may
not have been adequately trained. Therefore, in order to enhance the transition from theory to
practice, we recommend that intervention designers include a plan to assess and monitor
treatment fidelity based on the 5 domains proposed by Borrelli [40].

481 Using theory to design behaviour change interventions have been criticised, as they 482 specify what theoretical constructs (i.e. intentions) should be changed to change behaviour, but do not specify how constructs can be changed. However, systematic reviews have recently 483 started to identify links between theoretical constructs and BCTs, enhancing the effectiveness 484 of behaviour change interventions [63]. It has been suggested, those that target change 485 mechanisms at population, community and individual levels are the most effective [64], 486 suggesting that behaviour change interventions may benefit from drawing on a wider range of 487 theories than Social Cognition Models [20]. Recently, new approaches to behaviour change, 488 and the implementation and evaluation of interventions has been developed, in particular, the 489 Behaviour Change Wheel, COM-B model and the BCT taxonomy which helps build the bridge 490 between predicting behaviour and actual behaviour, by specifying the "active ingredients" of 491 the intervention, and this classification will facilitate replication of interventions [65]. The 492 Behaviour Change Wheel seeks to provide a framework, that other theories can be considered. 493 Social Cognition Models constructs mainly fall into the reflective motivation component of the 494 495 COM-B model and either minimally or not at all into the other 5 components [20]. The COM-B model is a holistic approach for changing behaviour, based on a model of an individual, 496 rather than a mechanistic process of identifying determinants of behaviour based on factors 497 accounting for variation in current behaviour between individuals [20]. The BCW incorporates 498 499 the COM-B model, TDF and BCT's in a systematic approach in designing an intervention. The BCW is gaining popularity in developing interventions in a range of health behaviours 500 including dietary behaviour [66,67]. Therefore, more research is needed, using new approaches 501

to understand dietary behaviour, and in the development and evaluation of complexinterventions [68].

504

505 Strengths and Limitations

506

A major strength of the current review is the use of the TCS, which allowed for a deeper 507 exploration of the extent of psychological theory driven interventions, and also our 508 understanding of shortcomings in the reporting and implementation on the use of psychological 509 theory. This review did not conduct a meta-analysis, however, the differences found in the 510 511 included studies populations, interventions and behavioural theories would make the average 512 effect across studies difficult to interpret [69]. Relevant studies may have been excluded due to selection criteria and search terms. For example, studies that are not in English but used 513 514 theory and relevant to this review would be missed and studies that failed to report they used a behaviour change theory. However, full articles were obtained for possible inclusion for 515 potentially relevant articles, even if theory was not explicitly mentioned in the abstract, further 516 minimising potential bias. Coding of the TCS may be subject to misclassification bias, 517 however, two researchers (DT&LS) interpreted and coded the TCS items to reduce any bias 518

519 Conclusion

To our knowledge this is the first review to examine psychological theory driven interventions that use a whole dietary pattern. We have found that, while all the included studies mentioned theory, total scores were mostly moderate, suggesting that theory had not been extensively applied to the design, implementation and evaluation of behaviour change interventions, and/or theory use was reported with insufficient detail. We recommend that future interventions explicitly link theory and outcome, to allow identification of the most

salient intervention techniques and behaviour change theory, to advance our understanding of 526 behaviour change. To enhance the transition from theory to practice, we recommend 527 researchers use a fidelity framework to guide the reporting of treatment fidelity in future 528 research. Mixed results were observed for the effectiveness of theory-based interventions. With 529 the small number of included studies, only one of which was high quality, findings should be 530 interpreted with caution. Future reviews should include both theory and non-theory 531 532 interventions, to provide evidence of the effectiveness of psychological based interventions compared to no theory use. 533

534

535 Abbreviations

536 BCC: Behaviour change consortium; BCT: Behaviour change techniques; COM-B: Capability opportunity, motivation and behaviour; CG: Control group; DASH: Dietary Approaches to 537 Stop Hypertension; DGI: Dietary guidelines index; EPOC: Cochrane effective practice and 538 organisation of care; HAPA: Health action process approach; HBM: Health belief model; HEI: 539 Healthy eating index; IG: Intervention group; MEDAS: Mediterranean diet adherence screener; 540 541 MIND: Mediterranean intervention for neurodegenerative delay; NCD: Non-communicable disease; PICOS: Population, intervention, comparison, outcome, study design; PRISMA: 542 Preferred reporting items for systematic reviews and meta-analysis; PROSPERO: International 543 544 prospective register of systematic reviews; RCT: Randomised controlled trial; SCT: Social cognitive theory; SDT: Social determination theory; TPB: Theory planned behaviour; TCS: 545 Theory coding scheme; TTM: Transtheoretical model; USA: United states of America; USDA: 546 547 Dietary guidelines for Americans; WHO: World health organisation.

548

549 **Declarations**

550	Ethics Approval and Consent to participate
551	Not applicable
552	Consent for Publication
553	Not applicable
554	Availability of Data and Material
555	All relevant data is included within the manuscript file
556	Competing Interests.
557	The authors declare they have no competing interests.
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560	Authors Contributions
561	DT/ LS designed the review and searched the databases for studies. DT/LS screened, quality
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563	revised the manuscript critically for intellectual content. All authors read and approved the final
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568	
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Figure 1: PRISMA flow chart identifying and screening studies, eligibility of studies andincluded studies n=9

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783 Supplementary information:

784 Supplementary file 1: PRISMA 2009 checklist

The PRISMA 2009 checklist is a 27 item checklist for the reporting of a systematic review
and/or meta-analysis, which include the title, abstract, methods, results, discussion, and
funding.

788