Transtheoretical model-based dietary interventions in primary care: a review of the evidence in diabetes

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Abstract

The objective of this study was to review the evidence concerning stage-based dietary interventions in primary care among persons with diabetes or an elevated diabetes risk. Search strategies were electronic databases and manual search. Selection criteria were randomized controlled studies with stage-based dietary intervention, conducted in primary care with at least 6 months of follow-up, and participants with either type 2 diabetes or with an elevated risk. The researchers evaluated trials for inclusion, extracted data and assessed study quality. Seven articles, based on five data sets, were included. These studies concentrated on cardiovascular diseases and being overweight, not diabetes. The quality of the studies was moderate to weak. Inadequacies in the reporting often involved unspecific information on the training of health care providers. Long-term positive outcomes (compared with controls) were found in total and monounsaturated fat intake, diastolic blood pressure, health status and wellbeing. The existing data are insufficient for drawing conclusions on the benefits of the transtheoretical model. More high-quality studies focusing on diabetes are needed, with greater attention to the training of providers and process evaluation. There is a need for a standardized appraisal tool for study evaluation, focusing separately on education interventions for patients and providers.

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Introduction

Lifestyle counseling based on behavior change models is often held to be more effective in promoting long-lasting behavior change than traditional counseling, since the models provide explanations for health-related behaviors [1]. The transtheoretical model (TTM, stage-based model) is one of the six most commonly cited behavior change models [2] frequently assumed to be more effective than a control situation [3]. TTM [4] consists of three core constructs ('stages', 'processes' and 'levels of change'), with the 'stage of change' describing the status of the person undergoing the change process. The stages form a continuum, and the person may move through the stages in a bidirectional manner. In order to help patients progress to the next stage, health care providers should identify the current stage and tailor their counseling strategies individually. TTM postulates that people at different stages have different needs for counseling:

(i) 'Pre-contemplation' (a healthier lifestyle is not yet considered) and

(ii) 'Contemplation' (thinking about behavior change): at these stages, the need is for

cognitive approaches that will increase the motivation for engaging in change.

(iii) 'Preparation' (intending to change behaviors, with no effective action): here the need is for behavioral-skills training.

(iv) 'Action' (modifying one's behaviors): the need at this stage is for specific interventions and concrete guidelines.

(v) 'Maintenance' (stabilizing change and avoiding relapse): the need is for assistance in preventing relapse and in consolidating gains [1, 5].

A good deal of criticism has been aimed at TTM, regarding, for example, the difficulty of applying the model to complex dietary behavior [3, 6–11]. Indeed, the effectiveness assumption does not appear to be founded on clear evidence. A previous review of five TTM-based lifestyle counseling studies [12] found positive changes in dietary fat intake in the stage-based groups, but the two studies in the review concerning fruit and vegetable intake showed considerable variation in the results obtained. The authors emphasized that the evidence was limited, due to the small number of studies. In addition, a large review carried out by Riemsma *et al.* [13] found mainly mixed effects in the five trials aimed at dietary change, with only two trials reporting significant effects that would support stage-based intervention. Within studies that incorporated multiple lifestyle interventions, there were five that included outcome measurements describing dietary behavior. In these studies, too, the results were contradictory.

Type 2 diabetes is on the increase, and its prevention requires effective lifestyle counseling [14].

The application of TTM in the diabetes context has been defended on the grounds that persons with diabetes who have been classified within the action or maintenance stages have been observed to display healthier eating patterns than those at other stages [15]. In diabetes counseling, TTM-based interventions have been reported as giving positive results [16, 17]. However, the studies in question are from hospital settings, despite the fact that the treatment of diabetes is usually a matter of primary health care. Because the primary care environment differs from the hospital setting, it is important to find evidence-based forms of counseling which will be particularly suited to the primary care setting. Although one previous review has examined TTM-based intervention studies performed within primary care settings [12], there are no previous reviews focusing on individuals with diabetes or with an elevated risk of diabetes. Thus, our first purpose was to review the evidence for using the TTM-based interventions in diabetes-related dietary interventions within primary care settings.

During the review process, we became aware that TTM-based intervention usually includes two kinds of intervention: (i) TTM-related training for 'providers', aimed at changing their counseling practices, and (ii) counseling for 'patients'. Nevertheless, the role of the provider is often neglected, despite the fact that information on the providers' ability to apply TTM properly is needed in drawing conclusions. The review by Riemsma *et al.* [13] revealed that only eight of the 37 stage-based intervention articles gave details on the providers' training (e.g. as nurses, physicians or dieticians). This is surprising, since learning new counseling practices is an extremely challenging undertaking [18]. With a view to expanding on the results obtained by Riemsma *et al.* [13], we also reviewed the information provided on the training of the providers.

Methods

A computerized literature search on the Internet was carried out in November 2005, using the following databases:

(i) Cochrane Central Register of Controlled Trials,
(ii) Cinahl,
(iii) Medline (from 1966),
(iv) PsycINFO and
(v) Embase.

The search strategy focused first of all on free-text words referring to (i) the TTM (e.g. 'transtheoretical', 'stage of change'), (ii) target behavior change (e.g. 'diet', 'change', 'modification') and (iii) type or

content of the intervention (e.g. 'counseling', 'client education'). In addition, database-specific Medical Subject Headings were included when appropriate (e.g. 'nutritional counseling', 'intervention trials'). The search was limited to 1983–2005. The selection of articles was restricted to those published randomized controlled trials (RCTs) carried out in primary health care settings (primary care, general practice, family practice, family medicine, internal medicine) that included a TTM-based dietary counseling intervention and a control condition. The intervention was defined as verbal advice, written materials or computerized counseling. The participants had to be adults with diagnosed type 2 diabetes, or elevated risk as indicated by a family history of diabetes, being overweight or obesity, physical inactivity, belonging to a particular race or ethnicity, having previously identified impaired fasting glucose or impaired glucose tolerance, polycystic ovary syndrome, dyslipidemia, elevated blood pressure levels or a history of vascular disease or gestational diabetes [19]. Studies with <6 months of follow-up and studies without a clear focus on diabetes-related diseases (e.g. studies primarily on cancer) were excluded. The search was not language dependent. However, only studies in English were included in the analysis.

The selection stages are described in Table I. The selection was performed separately by three of the authors. One of the authors performed a second search manually, examining the reference lists of the publications included and the reviews published. Two of the authors collated the data into the descriptive table. Any differences of opinion were resolved through discussion.

The computer-based search yielded 233 publications, of which 227 were excluded (reasons presented in Table I). Thus, the initial search gave us six RCTs with usable information. The manual search produced one more article. In all, a total of seven articles [20–26], based on five sets of research data [20 and 22, 21, 23 and 24, 25, 26], were included. In total, we found five articles [21, 23–26] that had not been included in previous reviews [12, 13].

The quality of the trials was assessed by means of the Quality Assessment Tool for Quantitative Studies [27, 28]. It defines eight component sections (selection bias, allocation bias, confounders, blinding, data collection methods, withdrawals and dropouts, analysis and intervention integrity) mentioning important issues that must be taken into account (see operationalization, Table II). The dictionary [29] that accompanies this tool was used as a guide in defining the items and the scoring process. After the reviewers had completed the quality form independently, the ratings were compared and a consensus reached by discussion. With the help of the dictionary, the information from the items on the form was transcribed into a summary of component ratings. Table II provides an example of the

Table I. *Exclusion criteria at different selection stages, and number of excluded articles (in total, 233 articles identified and 227 excluded)*

Exclusion criterion	Title, publication type and descriptors	Abstract	Full text and consultation with the authors	Total number
Focus group not a match	31	12	6	49
Setting not a match	8	7	5	20
Study theme not appropriate	69	6	4	79
Not an intervention trial	36	7	0	43
Follow-up <6 months	0	8	3	11
Intervention conducted before 1983	0	1	0	1
Intervention not based on TTM	0	1	2	3
Review article	17	3	0	20
Not in English	1	0	0	1
Total number excluded	162	45	20	227

Table II. *List of criteria for the quality assessment of RCTs on the effectiveness of stage-based dietary interventions in primary care: modification of critical appraisal tool developed by the Effective Public Health Practice Project* [28]

Component section	Items and response choices	Example of component ratings: rated as weak if[a]
Selection bias	1. Were the providers/patients likely to be representative of the target population? (very likely/somewhat likely/not likely) 2. What percentage agreed to participate? (80–100%/60–79%/<60%/not reported/not applicable)	1. Not likely or 2. Less than 60% or 1. Somewhat likely and 2. Not reported
Allocation bias	1. Was the method of random allocation stated? (Yes/No) 2. If yes, was it appropriate? (Yes/No) 3. Was the method of random allocation reported as concealed? (Yes/No)	1. No and 1. No and 1. No

Confounders	1. Were there group differences for important confounders? (Yes/No/Cannot tell/Not applicable)
	    'Providers': age, gender, attitudes toward counseling, counseling practices, postgraduate education in counseling
	    'Patients': age, gender, BMI/weight/waist circumference, dietary behavior, readiness to change dietary habits
	2. If yes, were they adequately managed in the analysis? (Yes/No/Not applicable)
	3. Were there important confounders not reported? (Yes/No)
		1. Cannot tell or
		1. Yes and 2. No and
		3. Yes
		    or
		1. Yes and
		2. No and
		3. No or
		1. No and
		2. Not applicable and
		3. Yes

Blinding	Were the outcome assessors blinded? (Yes/No/Not reported/Not applicable)	No or Not reported
Data collection methods	1. Were data collection tools shown or were they known to be valid? (Yes/No) 2. Were data collection tools shown or were they known to be reliable? (Yes/No)	1. No and 2. Yes or 1. No and 2. No
Withdrawals and dropouts	What was the percentage of participants completing the study? (80–100%/60–79%/<60%/Not reported/Not applicable)	Less than 60% or Not reported
Analysis	1. Was there a sample size calculation or power calculation? (Yes/Partially/No) 2. Was there a statistically significant difference between the groups? (Yes/No/Not reported) 3. Were the statistical methods appropriate? (Yes/No/Not reported) 4. What was the allocation unit? (Community/Organization or institution/Group/Provider/Client) 5. What was the analytical unit? (same than previous) 6. If the above two were different, was cluster analysis performed? (Yes/No/Not applicable) 7. Was the analysis performed with an intention to treat? (Yes/No/Cannot tell)	1. No and 2. Yes and 3. No and 4. + 5. Different unit and 6. No and 7. No

Table II. *Continued*

Component section	Items and response choices	Example of component ratings: rated as weak if[a]
Intervention integrity	1. What percentage of the providers/ participants received the intervention? (80–100%/ 60–79%/<60%/Not reported/Not applicable) 2. Was the consistency of the intervention measured? (Yes/No/Not reported/Not applicable) 3. Was contamination likely? (Yes/No/Cannot tell)	1. Less than 60% or Not reported and 2. No or Not reported and 3. Yes or Cannot tell
Total score[a]		Weak, moderate, strong

[a]Based on the dictionary for this particular tool [29].

scoring process; the factors taken into consideration in the complete scoring process are set out in the final pages of the dictionary [29]. The total quality score for the patient counseling interventions was estimated by calculating the median of the eight component sections.

The quality assessment tool was chosen because it takes into account intervention integrity, which is essential in theory-based studies. The content and construct validity of this tool have been established [30]. In this study, our aim was to evaluate the providers' training on TTM-based counseling. For this reason, we decided to analyze training as a second intervention. The same quality assessment tool was used for both forms of intervention. However, during the process we found this tool (as well as others) to be not completely suitable for assessing the training of the providers. As a result, we made some modifications that helped us to cover the essential quality factors (Table II). In the end, however, due to major information gaps in the reports we examined, we were unable to score the quality of the training given to providers.

We analyzed together those articles that were based on the same research data. We excluded one study [25] from the analysis of the providers' training because it did not consist of TTM-based counseling by providers. The remaining studies were included in the quality assessment according to a minimum of two reviewers. Strength of evidence (Table III) was defined on the basis of a quality assessment of patient counseling interventions.

Table III. *Levels of evidence [42]*

Strong	Consistent findings among multiple high-quality RCTs (two trials or more)
Moderate	Consistent findings among multiple weak- or moderate-quality RCTs (three trials or more) or with one high-quality RCT
Limited	One or two weak- or moderate-quality RCTs
Conflicting	Inconsistent findings among multiple RCTs
No evidence from trials	No RCTs

The reasons for not performing the meta-analysis were the poor quality of the studies included, differences between study protocols, the limited number of studies and the diversity of the outcomes. In drawing conclusions in the present review, we took into account the participants, the interventions, the controls and the outcomes and the methodological quality of the trials.

Results

Study characteristics

The characteristics of the seven studies included are set out in Table IV. The results presented in Table IV (first column from the right) focus solely on those

Table IV. *Characteristics of included dietary intervention studies (RCTs with >6 months of follow-up) in primary care*

Authors and country	Participants	Interventions	Follow-up	Outcome measurements (all)	Results related to dietary behaviors
Keller *et al.*, Germany [21]	Patients with newly discovered or previously untreated CV risk factors (*N* = 592). Mean age: 49 years in IG and 50 years in CG. Gender: 44% women in IG and 43% women in CG.	'Control group' (*n* = 318): usual care by physicians. 'Training of providers': physicians received one day of training in TTM. 'Counseling intervention' (*n* = 274): physicians counseled patients and handed out a stage-matched brochure at baseline visits and subsequent brochures during follow-up visits.	12 months, *N* = 267	1. SOC for healthy diet. 2. Diet quality. 3. SOC for smoking, exercise and stress management.	1. No significant changes. 2. No significant changes.
Steptoe *et al.*, UK [20]	Patients with CHD risk factors: regular cigarette smoking, high serum cholesterol or combined high BMI and low physical activity (*N* = 883). Mean age: 47 years. Gender: 406 men, 477 women.	'Control group' (*n* = 567): usual care by practice nurses. 'Training of providers': one nurse from each intervention practices was trained in TTM-based behavioral counseling. Nurses were trained by experienced psychologist and health educators to (i) assess a patient's SOC and to (ii) use attitude change, goal setting and specific behavioral advice to enable change. Three days training, with a retraining and refresher day after 6 months. 'Counseling intervention' (*n* = 316): nurse-led brief (maximum 20 min) behavioral counseling interventions to patients: if two risk factors, patient invited for three counseling sessions; if one risk factor, patient invited for two counseling sessions.	4 and 12 months, *N* = 471–518	1. Total fat intake (*N* = 471). 2. Systolic (*N* = 504) blood pressure. 3. Diastolic (*N* = 503) blood pressure, total cholesterol (*N* = 498), weight and BMI (*N* = 518). 4. Exercise and smoking behavior. 5. Smoking cessation.	1. Greater reduction in the IG (23.3 versus 15.2%). 2. Greater reduction only at 4 months, no difference at 12 months. 3. No differences.

Table IV. *Continued*

Authors and country	Participants	Interventions	Follow-up	Outcome measurements (all)	Results related to dietary behaviors
Steptoe *et al.*, UK [22]	Same as previous.	Same as previous.	12 months, $N = 520$	1. SOC for dietary fat reduction. 2. SOC for increased physical activity and smoking.	1. Substantial increase in the percentage of IG patients in action/maintenance stages (29 versus 17.7%).
Van der Veen *et al.*, The Netherlands [23]	Patients at elevated CV risk diagnosed with: (i) hypertension or (ii) type 2 diabetes or (iii) both of the above, + high total serum cholesterol + elevated total fat intake of energy and/or elevated saturated fat intake ($N = 143$). Mean age: 58 years. Gender: 73% female.	'Control group' ($n = 72$): usual care by family physicians (FP's) based on Dutch practice guidelines for FP's. 'Training of providers': FPs were supported by a protocol that included Prochaska's processes of change. The study manuals for the FPs and the dietitian were pre-tested and discussed by FPs and the dietitian in a pre-study group session. 'Counseling intervention' ($n = 71$): nutritional counseling from FP to patients based on stages of change with respect to reduction of total fat intake. Maximum of three consultations of ~10 min each. Patients who reached the preparation or action stage were referred to a dietician (the first consultation lasted 30–40 min; subsequent consultations 10–15 min each).	6 months ($N = 137$) and 12 months ($N = 130$)	1. Total energy intake. 2. Total fat and saturated fat intake. 3. Monounsaturated fat. 4. Unsaturated fat. 5. Cholesterol intake. 6. Weight, BMI, waist circumference, waist-to-hip ratio. 7. Changes in smoking status, physical activity and drug use.	1. SD at 6 months (0.8 MJ day^{-1}, $P = 0.01$). ND at 12 months. 2. SD at 6 and 12 months ($P = 0.00$). 3. SD at 6 and 12 months ($P = 0.00$ and 0.01). 4. ND. 5. SD at 6 months ($P = 0.00$), ND 12 months. 6. SD only in BMI and weight loss ($P = 0.01$) at 6 months. ND at 12 months.
Verheijden *et al.*, The Netherlands [24]	Same as previous.	Same as previous.	6 months ($N = 136$) and 12 months ($N = 129$)	1. Movement across SOC. 2. SOC for reduction of fat intake.	1. SD at 6 months ($P = 0.03$) but ND at 12 months. 2. SD at 6 months ($P < 0.001$), ND at 12 months.

Table IV. *Continued*

Authors and country	Participants	Interventions	Follow-up	Outcome measurements (all)	Results related to dietary behaviors
Verheijden *et al.*, Canada [25]	Patients with increased cardiovascular risk: hypertension, type 2 diabetes and/or dyslipidemia (*N* = 146). Mean age: 63 years. Gender: 55% male.	'Control group' (*n* = 73): usual care in family practice + in 4 and 8 months, results sheets with their BMI, blood pressure and cholesterol values. 'Counseling intervention' (*n* = 73): usual care + a personal registration code for the password-protected access to (i) a Web-based nutrition counseling (monthly SOC assessment tool for fat intake and information package for the particular SOC, self-assessment tool for dietary fat intake, heart-healthy recipes) and (ii) social support program (possibility to online conversation). After 4 months, patients received a reminder of their registration code, and in 4 and 8 months, they were sent results sheets with their BMI, blood pressure and cholesterol values.	4 months (*N* = 134) and 8 months (*N* = 130)	1. SOC for dietary fat 2. Social support 3. BMI, waist-to-hip ratio 4. Systolic and diastolic blood pressure 5. Total cholesterol, HDL, LDL, triglycerides	1. ND in distribution across SOC. 2. ND. 3. ND. 4. ND. 5. ND.

Table IV. *Continued*

Authors and country	Participants	Interventions	Follow-up	Outcome measurements (all)	Results related to dietary behaviors
Logue *et al.*, USA [26]	Primary care patients with BMI >27 or elevated waist-to-hip ratio (N = 665). Age: 40–69 years. Gender: predominantly female.	'Control group' (n = 336): basic care: patients were asked to provide anthropometric, dietary and exercise data every 6 months. After each assessment, a dietician provided 10 min of traditional counseling, written dietary and exercise prescriptions and advice for discussion with their physician. They were also paid USD 25. 'Training of providers': weight-loss advisor was trained to apply to the processes of change that corresponded to patient's SOC profile. A part-time pharmaceutical representative was trained to provide academic detailing to physicians on the use of the SOC profiles, the processes of change, and how to use a small SOC flip chart during the counseling. 'Counseling intervention' (n = 329): patients received basic care + periodic SOC assessments for five target behaviors (every 2 months), also received SOC mailings and brief (15 min) monthly telephone calls from a weight-loss advisor. Implementation of the weight-loss telephone protocol was monitored by the project psychologist who advised the weight-loss advisors to interact with problematic patients.	24 months (exact numbers were not reported)	1. Daily energy intake. 2. Weight, waist circumference. 3. Blood lipids and blood pressure. 4. SOC for increased dietary portion control, decreased dietary fat, increased fruit and vegetable consumption.	1. ND. 2. ND. 3. ND. 4. Measured only for IG, cannot be compared with CG.

IG = intervention group; CG = control group; SOC = stages of change; CHD = coronary heart disease; CV = cardiovascular; ND = non-significant difference; SD = significant difference; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

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outcome measures that are related to dietary behaviors (excluding e.g. outcomes concerning physical activity).

The participants in six of the studies [21, 20 and 22, 23 and 24, 25] had elevated cardiovascular risk factors, and in one further study [26], the participants consisted of overweight persons. The purpose of the studies was to address risk factors and behaviors such as high fat intake and overweight. Simple addition of the raw numbers of participants in the seven studies examined would give a total of 4047 persons. However, there are in fact only five sets of data (the same material having being used for more than one study), with a total of 2429 participants in the five sets. The mean number of participants per study was 486. Overall, the participants were mainly middle-aged and older adults. In four studies, the participants were predominantly women [21, 23 and 24, 26]. The mean follow-up time was 15 months. The primary outcomes involved lifestyle behavior, stages of change and physiological measures. Long-term outcomes such as incidence of diabetes were not examined.

As can be seen in Table IV, all the control groups received the usual care, but the content and intensity (duration and frequency) of counseling varied or were not reported. In most of the studies [21, 20 and 22, 23 and 24, 25], usual care was defined as 'usual care by physicians/practice nurse' which provides no information on the intensity of the care. There was also variation in the usual care providers, who could be physicians [21, 23 and 24, 25], nurses [20 and 22] or dieticians [26]. The intervention groups received counseling with methods and intensities that were not comparable, and the intensity differed, not only between the studies but also within the studies. The content of the counseling varied between the trials: three studies [23 and 24, 25] focused only on dietary counseling, while other studies also included counseling on, for example, exercise and smoking. Furthermore, the intervention counselors were heterogeneous (physicians, nurses, dieticians, weight-loss advisors or a combination of these), and in one study [25], the actual intervention consisted of TTM-based websites, questionnaires and monthly information packages.

Methodological quality of the trials

The results of the quality assessment of patient education and providers' training are presented in Table V. Regarding the patient education interventions, two of the studies were graded as of moderate quality [23 and 24, 25] and three as of weak quality [21, 20 and 22, 26]. Inconsistencies were found, for example, in confounders, blinding and data collection methods. Details regarding randomization methods and allocation concealment were often not accurately reported (e.g. whether the providers were randomized before the patients were selected, allowing the possibility that the providers in an intervention group might be predisposed to recruit motivated patients). None of the six trials in which there was personal contact between patients and provider examined the effect of the providers' training. Furthermore, the degree, content and methods of the providers' training varied or were inadequately reported (Table V). The procedures for recruitment of the providers were often unclear, making it impossible to draw conclusions on how representative the providers actually were. It was notable that the process evaluation of patient education (how the providers actually counseled) was not reported or was inadequately reported, making it difficult to ascertain whether the intervention was properly stage based. Two studies [21, 26] in particular highlighted the providers' poor adherence to the TTM protocol. Steptoe *et al.* [22] also pointed out that their intervention included a range of behavioral techniques that were also used outside the TTM. For this reason, it cannot be concluded that benefits were due to the use of TTM [22].

Level of evidence

The number of trials included was small, and the studies assessed a variety of outcome measures. Consequently, strength of evidence had to be defined on the basis of only one to three trials, which were weak or of moderate quality (Table VI). Based on the three trials [23 and 24, 25] with 6–8 months of follow-up (intermediate effectiveness, Table VI), there was limited evidence to indicate that stage-based

Table V. *Methodological quality assessment using a modified critical appraisal tool developed by the Effective Public Health Practice Project [29]*

Component section	Keller et al. [21]		Steptoe et al. [20, 22]		Van der Veen et al., Verheijden et al. [23, 24]		Logue et al. [26]		Verheijden et al. [25]
	Education		Education		Education		Education		Education
	1	2	1	2	1	2	1	2	2
a) Selection bias	w	w	w	w	w	m	w	w	w
b) Allocation bias	w	-	m	-	m	-	-	s	s
c) Confounders	-	?	-	m	-	s	-	w	w
d) Blinding	-	w	-	w	-	w	-	?	s
e) Data collection methods	-	i	-	i	-	i	-	i	?
f) Withdrawals and dropouts	?	w	-	w	-	s	-	m	s
g) Analysis	-	m	-	m	-	s	-	s	s
h) Intervention integrity	w	w	m	m	?	m	?	w	w
Number of quality grades (a–h)									
Weak		4		3		1		3	4
Moderate	*	1	*	3	*	2	*	1	0
Strong		0		0		3		2	4
Median of quality grades		W		W/M		M/S		W/M	M
Total score**	*	Weak	*	Weak	*	Moderate	*	Weak	Moderate

Education 1 = training of providers in use of TTM; education 2 = patient education to maintain healthy diet; w = weak; m = moderate; s = strong;? = unclear; - = not studied/performed; i = incomplete; strong quality (S), moderate quality (M), weak quality (W).*The total quality score for the training of providers in the use of TTM was not estimated because of the high degree of missing information. **The total quality score for patient education was estimated by calculating the median of the eight criteria (a–h). If the median fell between two scores, the lower quality score was chosen due to unclear and inadequate sections in the quality criteria.

intervention was more effective than usual care in terms of total energy intake, total fat intake, saturated fat intake, monounsaturated fat intake, weight and movement across stages of change. On the other hand, there was also limited evidence that there was no difference concerning unsaturated fat intake, diastolic and systolic blood pressure, waist circumference or waist-to-hip ratio at 6–8 months. The evidence concerning body mass index (BMI), lipid values and distribution across stages of change was conflicting. However, it must be emphasized that overall, the evidence pertaining to the 6–8 months of follow-up was weak, since all the outcomes were based on only one study (Table VI).

Based on the five trials that had 12–24 months of follow-up (long-term effectiveness, Table VI), there was limited evidence that stage-based interventions were more effective than usual care in terms of total fat intake [20, 23], monounsaturated fat intake [23] and systolic blood pressure [20]. On the other hand, there was also limited evidence that stage-based interventions were not more effective in terms of total energy intake [23, 26], saturated fat intake [23], unsaturated fat intake [23], BMI [20, 23], diastolic blood pressure [20], blood pressure [26], waist circumference or waist-to-hip ratio [23, 26], early weight loss and regain [26] and distribution across stages of change [24]. There was moderate evidence that there was no difference in terms of weight and lipid values [20, 23, 26]. Surprisingly, the evidence concerning movement across stages of change was conflicting [21, 22, 24].

Table VI. *Strength evidence*

A) Outcome measure	B) Studies	C) 6–8 months		D) 12 months		E) 24 months		F) Level of evidence at	
		FC	NC	FC	NC	FC	NC	6 months	12–24 months
Total energy intake	2	Van der Veen [23]			Van der Veen [23]	Logue [26]		Limited, FC	Limited, NC
Total fat intake	2	Van der Veen [23]		Van der Veen [23], Steptoe [20]				Limited, FC	Limited, FC
Saturated fat intake	1	Van der Veen [23]			Van der Veen [23]			Limited, FC	Limited, NC
Monounsaturated fat intake	1	Van der Veen [23]		Van der Veen [23]				Limited, FC	Limited, FC
Unsaturated fat intake	1		Van der Veen [23]		Van der Veen [23]			Limited, NC	Limited, NC
Weight	3	Van der Veen [23]			Van der Veen [23], Steptoe [20]	Logue [26]		Limited, FC	Moderate, NC
BMI	3	Van der Veen [23]	Verheijden [25]		Van der Veen [23], Steptoe [20]			Conflicting	Limited, NC
Systolic blood pressure	2		Verheijden [25]	Steptoe [20]				Limited, NC	Limited, FC
Diastolic blood pressure	2		Verheijden [25]		Steptoe [20]			Limited, NC	Limited, NC
Blood pressure	1					Logue [26]		No RCTs	Limited, NC
Waist circumference or waist-to-hip ratio	3		Van der Veen [23], Verheijden [25]		Van der Veen [23]	Logue [26]		Limited, NC	Limited, NC
Lipid values	4	Van der Veen [23]	Verheijden [25]		Van der Veen [23], Steptoe [20]	Logue [26]		Conflicting	Moderate, NC
Early weight loss and regain	1					Logue [26]		No RCTs	Limited, NC
Distribution across SOC	2	Verheijden [24]	Verheijden [25]		Verheijden [24]			Conflicting	Limited, NC
Movement across SOC	3	Verheijden [24]		Steptoe [22]	Keller [21], Verheijden [24]			Limited, FC	Conflicting

A) outcome measures assessed; B) number of studies assessing a particular outcome; C–E) results of the trials; F) defined level of evidence. FC = favorable change; NC = no significant change.

Discussion

The present review revealed that there is a lack of stage-based dietary counseling studies in primary care settings with a clear focus on type 2 diabetes prevention and treatment. Indeed, there are not many diabetes-related trials with any other main focus (e.g. cardiovascular diseases, obesity). The studies we examined also displayed a number of defects related to data on providers' and patient education and process evaluation. In view of these considerations, it is impossible to draw conclusions concerning the benefits of stage-based dietary counseling (in comparison with usual care) in primary care settings. However, we must emphasize that an absence of data does not equal lack of effectiveness.

The only favorable long-term differences between the groups concerned total fat intake, monounsaturated fat intake and systolic blood pressure. However, no firm conclusions can be drawn from these differences, since only one or two trials addressed these outcomes. Riemsma et al. [13] suggested that there is limited evidence concerning the benefits of TTM-based counseling. Furthermore, Van Sluijs et al. [12] provided no substantial evidence for the effect of stage-based dietary interventions in primary care. If we add our observations to the previous findings, we are led to speculate on the reasons for the popularity of TTM [3], given the lack of scientific evidence. Clearly, any recommendations for using the model should be evidence based.

Nevertheless, many issues of study quality and process evaluation arose in our analysis. We found that the training of providers played a very minor role in the studies, despite the fact that new counseling practices often disseminate slowly among professionals—or sometimes not at all [31, 32]. It seemed that most of the studies did not even recognize that two separate interventions, among providers and patients, were involved. In addition, despite several published quality assessment tools for RCTs [33, 34], we found that the existing tools were designed for evaluating patient counseling interventions and did not address the education and training of providers. Despite this, the tool we used [28] is applicable, if modified. Typical deficiencies also emerged (e.g. [35, 36]) in the reporting of RCTs, and possibly in the way they were conducted.

On the basis of these observations, we would draw attention to several significant issues for future studies. First of all, it is important to describe the content and methods included in the education and training given to providers. Furthermore, in order to reduce variation arising from individual differences among providers, it would be important to determine a baseline for the characteristics of the providers. This requirement is based on many potential confounding factors, such as counselors' attitudes, postgraduate education, counseling practices and readiness to change such practices. The point is crucial, especially with cluster-level interventions, when baseline differences between health care settings (e.g. resources, counseling practices) are likely to exist. Furthermore, the evaluation of providers' training should include behavior change outcomes, since it appears that counselors may quickly grasp the idea of TTM, yet may need intensive training to become skilled facilitators [6]. Miller and Mount [18] have also pointed out that training should not focus solely on developing new counseling practices but should, concurrently, selectively suppress old ones. In any case, underestimating the providers' training constitutes a waste of resources, since it contributes to exceedingly unreliable research findings. The cost-effectiveness of brief training sessions must be questioned if they are insufficient to produce significant changes in counseling practice.

One interesting finding was the variation across and within studies. For example, in one study [20, 22], there were one to three counseling sessions lasting no >20 min. In contrast, another study [26] provided counseling by a dietician and, optionally, by a physician, with monthly telephone calls and mailed materials extending >2 years. An example of intra-study variation arose in a study that provided one to three consultations with a physician, but where only those patients that had reached the preparation or the action stages were referred also to a dietician [23 and 24], in accordance with TTM.

As a reviewer, it is difficult to draw conclusions on the effectiveness of stage-based counseling when the counseling protocols include so much variation. If the benefits of using TTM-based counseling in diabetes management and prevention are to be proved, future studies will have to have protocols that are more standardized.

In the majority of the trials, because the idea of TTM is to counsel only for behaviors for which a person is at risk [37], not every participant automatically received dietary counseling. Due to this, we had to speculate on whether the analysis on effectiveness concerning dietary habits also included people who did not receive any dietary counseling. This aspect was not dealt with in any of the trials. In order to study effectiveness reliably, statistical analysis should be confined only to individuals who actually received dietary counseling at the time of intervention.

The inadequate description of usual care also raises questions, since outcomes are closely related to the intensity of the intervention [38]. In cases where usual care is not properly described, it is possible that favorable differences between the groups could simply be the result of more intensive counseling in the intervention groups, not of stage-based methods. It should be borne in mind that the mere awareness that tailored intervention is being given to patients might enhance its effectiveness [7]. In addition, progress by patients can also be due to inherent change processes, when patients identify themselves as being at a particular stage [7]. At the same time, it should be noted that progress of this kind could have taken place among both types of group (control and experimental) covered in our review, since the participants in the control groups, too, completed the questionnaire concerning their readiness to change and identified their stage.

One interesting finding was that in a single study [24] assessing the long-term change in distribution across the stages of change, no significant change was found. In respect of the three studies that assessed movement across the stages of change, only one study [22] found significant change. According to TTM, it is not possible to effect life-style changes without such movement. In this context, we would have to question the ability of stage-based counseling to promote such movement—yet we also need to ask whether the counseling was truly based on the principles of TTM [10, 21, 39]. It is inappropriate to use TTM without evidence on its effectiveness. On the other hand, condemnation of the model is unjust if it is based on possibly inadequate implementation of the model. It seems that the only way to resolve this uncertainty is to make a proper process evaluation of the counseling sessions, using direct observation of counseling [18]. None of the studies included had carried out this kind of evaluation, a point which leaves many questions unanswered. If the model is to be considered for future application, it will be extremely important to mount a concentrated effort with a view to collecting scientific evidence concerning its benefits.

Limitations of the study

There are several factors that might affect the results of this review. The findings are based on only seven articles and five sets of data. Because of limited time, we decided not to contact the authors for additional information if an article was inadequate. Nor can we exclude the possibility of publication bias. It is also possible that our literature search failed to identify all the potential articles, given that no universally applicable definition of primary health care has been formulated so far [40]. However, we were able to find five articles that were not included in these earlier reviews [12, 13]. On the other hand, our computer-based search failed to find at least one study published in an Internet-based periodical [25], probably because this online periodical was not included in the databases used for this review. It might be advisable to include search engines (e.g. Google Scholar) in search strategies, as has been recommended [27] for the location of unpublished and difficult-to-find literature.

Despite using a validated critical appraisal tool, we found that the quality assessment process was very challenging, due to several choices of interpretation.

For example, selection bias was defined as unlikely if 'the authors have done everything reasonably possible to ensure that the target population is represented' [29]. Based on the reports, it is difficult to say what actually is 'everything reasonably possible'. In conclusion, there still seems to be a need for better assessment tools. In addition, the dispersal of reported results and evaluations across separate articles is problematic from the reviewer's point of view, when one is analyzing the quality of studies. It would be helpful if authors were to make known their intention to further report on their research results in any subsequent publications.

Conclusions

There are currently too few studies of sufficient quality to determine the benefits of using stage-based dietary counseling, as opposed to traditional counseling, in primary care settings, among individuals with diabetes or with an elevated risk of diabetes. Because the effectiveness of TTM-based counseling is strongly dependent on the effectiveness of the education and training given to providers, such studies should be treated as studies with two separate educational interventions, each with its own evaluation. Thus, we would support a previous conclusion [41], i.e. that a modified critical appraisal tool should be created for evaluating studies with two separate educational interventions. In order to assess whether the providers have truly changed their counseling behavior, a multilevel assessment of behavior change outcomes should be included as part of an evaluation of the outcomes of providers' training. In addition, a careful process evaluation of the counseling sessions is required.

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Conflict of interest statement

None declared.

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