





## Original Article

# Transtheoretical model for lifestyle changes in older persons: a systematic review protocol

Melissa Côrtes da Rosa,<sup>1</sup>  Carolina Böettge Rosa,<sup>1</sup>  Raquel de Melo Boff,<sup>2</sup>   
Margareth Silva Oliveira,<sup>3</sup> and Carla Helena Augustin Schwanke<sup>1,4</sup> 

<sup>1</sup>Graduate Program in Biomedical Gerontology, School of Medicine, Pontifical Catholic University of Rio Grande do Sul (PUCRS), Rio Grande do Sul, Brazil. <sup>2</sup>Universidade de Caxias do Sul (UCS), Rio Grande do Sul, Brazil. <sup>3</sup>Graduate Program in Psychology, School of Health and Life Sciences, Pontifical Catholic University of Rio Grande do Sul (PUCRS), Rio Grande do Sul, Brazil. <sup>4</sup>Institute of Geriatrics and Gerontology, Pontifical Catholic University of Rio Grande do Sul (PUCRS), Rio Grande do Sul, Brazil

Address for correspondence: Carla Helena Augustin Schwanke, Institute of Geriatrics and Gerontology, Pontifical Catholic University of Rio Grande do Sul (PUCRS), Av. Ipiranga, 6681–Prédio 40, sala 806, CEP: 90.619-900, Porto Alegre, Rio Grande do Sul, Brazil. [schwanke@pucrs.br](mailto:schwanke@pucrs.br)

Adherence to lifestyle changes is a major challenge for healthcare professionals. The transtheoretical model (TTM) was proposed to promote behavioral changes, used in different health conditions (smoking, alcoholism, drug addiction, and obesity) and age groups. However, the effectiveness of the model in older persons is not yet known. This systematic review protocol follows the PRISMA-P guidance. The question the review will address is, Are interventions based on the TTM, compared with conventional interventions, associated with lifestyle changes in older adults? Databases MEDLINE/PubMed, EMBASE, LILACS, CENTRAL, WoS, and PsycINFO will be searched. Randomized clinical controlled trials and quasi-experimental studies describing the effectiveness of TTM-based interventions in changing the lifestyle of individuals aged 65 and over, compared with conventional interventions for lifestyle changes, will be included. Studies that do not address the stages of change characteristic of TTM or that use pharmacological interventions as a comparator will be excluded. Reviewers independently will screen papers for eligibility criteria, and, extracting data, assess the risk of bias for included studies and will evaluate the overall quality of evidence (GRADE system). If possible, a meta-analysis will be conducted. Otherwise, a narrative synthesis will be prepared according to the SWiM guideline.

**Keywords:** biobehavioral science; transtheoretical model; healthy lifestyle; health behavior; aged

## Introduction

According to the United Nations,<sup>1</sup> the old adult population increased by 9% in 2019, with a projected 16% increase in 2050; therefore, one in six people worldwide will be aged 65 or more. This significant increase is due to the reduction in birth rates, the global success of public health policies, the reduction of mortality, and the increase in life expectancy.<sup>2</sup> However, it is at this stage of life that the individual most uses health services, and the difficulty of access in developing countries can aggravate chronic noncommunicable diseases.<sup>3</sup>

The reduction of modifiable risk factors through adherence to healthy behaviors can prevent and, in some cases, treat these conditions.<sup>4</sup> In order to reduce risk factors for chronic diseases, the World Health Organization (WHO)<sup>5</sup> recommends a change in lifestyle, which includes behaviors, such as healthy eating, adherence to physical activity, reduced use of alcohol, and smoking cessation.<sup>4,6,7</sup> A cohort study followed 1,810 older persons individuals for 18 years in Sweden and showed that initiating changes in habits after 75 years of age can bring benefits in quality of life and increased survival, adding 5 years for women and 6 years for men.<sup>8</sup>

In this sense, the transtheoretical model (TTM) can be useful in changing the lifestyle of older persons. TTM is an approach initially developed to help a group of adults over 50 years old to quit smoking.<sup>9</sup> It is a motivational intervention model that focuses on specific objectives for each problem behavior, such as starting, modifying, or ceasing.<sup>10,11</sup> For TTM, what promotes behavior change is motivation, intrinsic and extrinsic, which depends on a series of variables, such as the stages of change, processes of change, self-efficacy, pros, and cons.<sup>11</sup> The TTM authors isolated mechanisms of change from different psychological approaches and concluded that change is a process, not a product, and it depends on how ready the individual is and how each person processes the change.<sup>9</sup> Thus, five stages have been described (precontemplation, contemplation, preparation, action, and maintenance) that refer to thoughts and behaviors about change.<sup>12</sup>

After identifying in which stage the individual is to perform a particular change, it is possible to intervene from the use of change processes. For TTM, the 10 processes of change, five cognitive (consciousness raising, dramatic relief, environmental reevaluation, self-reevaluation, and social liberation) and five behavioral (self-liberation, counterconditioning, helping relationships, reinforcement management, and stimulus control), are considered resources that will help people moving between stages. Variables, such as self-efficacy and evaluation of pros and cons, are configured as mediators of change as they motivate decision making and the maintenance of new habits.<sup>12</sup>

A preliminary search on PROSPERO, MEDLINE (via PubMed–MEDLINE/PubMed), and Cochrane Database of Systematic Reviews identified studies that describe treatments based on TTM with positive effects on adherence to a healthy lifestyle in different populations.<sup>13–16</sup> Specifically with individuals over 65 years old, only two reviews were found: one on adherence to medications and the other on physical activity.<sup>17,18</sup>

Although reviews addressing the use of TTM in older persons have been found,<sup>17,18</sup> none have proposed to assess the effects of TTM on the set of behaviors related to the lifestyle proposed by the WHO.<sup>5</sup> In addition, as an important conclusion of the literature, the review studies focus on evaluating only the stages of change.<sup>13–16</sup> However, the extended use of the TTM change processes, as

well as self-efficacy and the assessment of pros and cons, can be an important predictor of the success of interventions with older persons.<sup>17</sup>

Thus, this study aims to gather randomized controlled trials and quasi-experimental studies in order to evaluate the effectiveness of TTM-based interventions compared with conventional interventions to assist older persons to adhere to a healthy lifestyle. In this sense, the expected outcomes in this review are adherence to healthy eating, introduction or increase in the practice of physical activity, reduction in alcohol use, and smoking cessation. In addition, aggregate data on the impact of interventions on anthropometric measurements, body composition, and biochemical tests (biochemical profile) are included.

## Methods

The protocol is reported in line with the preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P)<sup>19</sup> and is registered in PROSPERO (CRD42021213869).

## Eligibility criteria

### *Inclusion criteria*

**Participants.** This review will consider studies whose participants are 65 years and older and mixed populations (individuals under and over 65 years). Only the data from older persons will be collected.

**Intervention(s).** This review will consider studies that evaluate interventions based on the TTM, characterized by the identification of the five stages of change (precontemplation, contemplation, preparation, action, and maintenance) by Prochaska and DiClemente.<sup>20</sup>

**Outcomes measures.** Studies that report at least one of the outcome measures will be included.

**Primary outcomes.** Studies with outcomes related to lifestyle change will be included:<sup>5</sup> changes in diet adherence and food consumption (e.g., increased consumption of fruits and vegetables, increased fiber intake, and reduced fat, sugar, and salt intake); changes in physical activity (e.g., weekly time or frequency); changes in alcohol consumption (e.g., withdrawal or reduced consumption); and changes in smoking (e.g., cessation or reduced use).

**Secondary outcomes.** In addition, the following outcomes related to lifestyle change and major

outcomes will be considered: changes in anthropometric measurements (e.g., reduction in waist circumference, arm circumference, neck circumference, and/or hip circumference); changes in body composition (e.g., reducing weight in kg or reducing weight percentage, increasing lean mass, and reducing fat mass); changes in the biochemical profile (e.g., reduction of triglycerides, total and LDL cholesterol, glucose, and increased HDL).

**Study design.** Randomized controlled trials and quasi-experimental studies comparing TTM to a conventional lifestyle change intervention or no intervention will be considered.

**Timing and setting.** Studies with preintervention and immediate postintervention evaluation, lasting at least 12 weeks of follow-up, will be included.

#### *Exclusion criteria*

Studies that do not address the stages of change characteristic of TTM or that use pharmacological interventions as a comparator will be excluded.

#### **Information sources**

The search strategy will be performed from April 2021. The following electronic databases will be searched: MEDLINE/PubMed, Excerpta Medica dataBASE (EMBASE), Latin American and Caribbean Health Sciences Literature (LILACS), Cochrane Central Registry of Controlled Trials (CENTRAL), Web of Science (WoS), and American Psychological Association Database (APA PsycInfo).

The reference lists of studies selected for critical appraisal will be screened to identify potential studies that meet the inclusion criteria. The search for gray literature will be done in clinical trial registry bases (ClinicalTrials.gov and the Brazilian Clinical Trials Registry, ReBEC).

#### **Search strategy**

The MEDLINE/PubMed search strategy will be adapted for use in other electronic databases (see Supplementary Material: Appendix I, online only). The search will not be limited by date or language, and other restrictions will not be placed. The controlled vocabulary will be used whenever possible (MeSH term for MEDLINE/PubMed, LILACS, CENTRAL, WoS, and APA PsycInfo; Emtree for EMBASE). The search strategy will

combine terms and controlled vocabulary about (1) “transtheoretical model” and (2) “aged.”

#### **Study records**

##### *Data management*

The Covidence software will be used for importing and deduplicating records, title/abstract screening, full-text screening, quality assessment (for randomized clinical trials), and data extraction. Covidence is a data management tool designed for the synthesis of health evidence.<sup>21</sup>

Two reviewers independently (M.C.R. and C.B.R.) will screen papers for eligibility criteria, and will extract data, assess the risk of bias for included studies, and will evaluate the overall quality of evidence. In case of doubt, a third senior author (C.H.A.S.) will be consulted.

##### *Selection process*

The authors, independently, will perform the initial screening of titles and abstracts and, according to the selection criteria, will classify the studies into eligible, potentially eligible, and ineligible. The priority sequence of the eligibility criteria will be intervention, participants, outcomes, study design, and absence of exclusion criteria.

The result of the research and the selection process (number of studies found, duplicates, and studies excluded and included) will be recorded, reported in the final systematic review, and presented in a flow chart.<sup>22</sup>

##### *Data collection process*

Data will be extracted using a standard form to minimize the risk of errors and to ensure that all data are extracted. The extracted data will include specific details about the characteristics of the study (title, authors, country, and year of publication), of the participants (average age and sex distribution), methods (study design, type, and duration of the intervention, comparator, and size of the sample), description/details of the intervention (location, stages of change, change processes, self-efficacy, and assessment of pros and cons), dropouts (all groups), outcomes related to the change in the lifestyle of older persons (healthy eating, physical activity, control or cessation of alcohol consumption, and smoking cessation), additional outcomes related to changes in lifestyle (anthropometric changes, body composition, and biochemical profile), and results (mean, standard deviation or percentage in

the pre- and post-test, and differences between the intervention and control groups).

The data extraction form will be tested on five articles to allow reviewers to practice. Authors of papers will be contacted to request missing or additional data, where required.

### Risk of bias assessment

Three tools will be used to assess the risk of bias of the studies: Revised Cochrane Risk of Bias (RoB 2.0) for randomized clinical trials,<sup>23</sup> Revised Cochrane risk-of-bias tool for cluster-randomized trials (RoB 2 CRT) for cluster-randomized clinical trials,<sup>24</sup> and Risk of Bias in Non-randomised Studies – of Interventions (ROBINS-I) for nonrandomized clinical trials.<sup>25</sup>

The RoB 2.0 tool is structured into five domains: (1) bias arising from the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in the measurement of the outcome; and (5) bias in the selection of the reported result. Each domain has signaling questions to obtain information about the relevant characteristics for the assessment of the risk of bias in the studies, with five answer options: yes; probably yes; probably no; no; and no information. The possible risk of bias judgments: low risk of bias, some concerns, and high risk of bias.<sup>23</sup>

In the RoB 2 CRT tool, only one domain was added for cluster-randomized studies (1b-risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial).<sup>24</sup>

ROBINS-I, on the other hand, evaluates nonrandomized studies through seven domains: (1) bias due to confounding; (2) bias in selection of participants into the study; (3) bias in the classification of interventions; (4) bias due to deviations from intended interventions; (5) bias due to missing data; (6) bias in measurement of outcomes; and (7) bias in selection of the reported result. The possible risk of bias judgments: low, moderate, serious, or critical risk of bias, or no information.<sup>25</sup>

The results of our assessment will be presented in a graph or table in the data summary.<sup>22</sup>

### Data synthesis

Data will be presented in a narrative, using the Synthesis Without Meta-analysis (SWiM) guideline.<sup>26</sup> Tables and figures will be used for the auxiliary

presentation of the data, when appropriate. The meta-analysis will be performed if there are at least two studies that answer the same question, use at least one outcome in common, and have similar study designs.<sup>27</sup>

The analyses will be conducted using the random effects model, with DerSimonian and Laird as the variance estimator. Continuous data (such as anthropometric measurements and biochemical tests) will be summarized as a difference from gross averages, and categorical data as a relative risk. If necessary, for continuous outcomes assessed by different scales or instruments, the data will be summarized as a difference from standardized means (Cohen's *d*). In addition to the summary estimate, the 95% confidence interval (CI) will be determined for each outcome.

If possible, a subgroup analyses will be performed considering sex, age group, and stage of the intervention. The analyzes will be performed using the R software, meta package (R Foundation for Statistical Computing, Vienna, Austria).<sup>28</sup>

### Heterogeneity

Heterogeneity will be assessed statistically using standard  $I^2$  tests.<sup>29</sup> In the presence of substantial heterogeneity, exploratory analyses will be performed, such as subgroup analyses (according to sex, age group, stage of change, and risk of study bias).

### Publication bias

The evaluation of publication bias will be performed using funnel charts that will be generated if at least 10 studies are eligible for outcomes of interest.<sup>30</sup> When appropriate, statistical tests will be performed to analyze the asymmetry of the funnel charts, such as the Egger and Begg test.<sup>31</sup> *P* value of <0.05 will be considered statistically significant.

### Quality of evidence or confidence in cumulative evidence

Primary outcomes will be analyzed for the strength of evidence according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool.<sup>32</sup> This tool consists of five domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias, ranging from high to very low quality of evidence.

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## Author contributions

M.C.R., M.S.O., and C.H.A.S. conceived the study. M.C.R. and C.B.R. developed and executed the search strategy. M.C.R., R.M.B., C.B.R., and C.H.A.S. designed eligibility assessment and data extraction forms. M.C.R., M.S.O., R.M.B., C.B.R., and C.H.A.S. planned literature search strategy. M.C.R. prepared the first version of this article. M.S.O., R.M.B., C.B.R., and C.H.A.S. critically reviewed the manuscript. M.C.R., M.S.O., R.M.B., C.B.R., and C.H.A.S. reviewed and approved the final version of the manuscript.

## Supporting information

Additional supporting information may be found in the online version of this article.

## APPENDIX I

## Competing interests

The authors declare no competing interests.

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