

Evaluations of Validity and Reliability of a Transtheoretical Model for Sedentary Behavior among College Students

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Objective: To evaluate the measurement properties of the Transtheoretical Model (TTM) questionnaire for sedentary behaviors among college students and to examine the validity and reliability of the developed TTM questionnaire. **Methods:** Overall, 225 college students were recruited. For the 2-week test-retest reliability, a random sub-sample (N = 108) of the participants was used. **Results:** Statistically significant differences were found across the stages on the tests of concurrent ($\chi^2 = 25.0$, $p < .001$) and con-

struct ($p < .01$) validity. In addition, the internal consistency reliability (Cronbach alphas from .73 to .88) and test-retest reliability (intra-class correlation coefficients ranging from .80 to .94) were high for the questionnaires. **Conclusions:** These results demonstrate high validity and reliability of the TTM questionnaire when applied to sedentary behavior.

Key words: sedentary; TTM; validity; reliability

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Sedentary behaviors refer to any tasks during waking hours that require an energy expenditure of less than 1.5 metabolic equivalents (METs), including sitting or reclining postures such as when watching TV, using a computer, playing a video game, reading, or listening.¹ Sedentary behaviors have emerged as a primary public health concern due to possible deleterious health consequences independent of current physical activity levels, including obesity, type 2 diabetes, cardiovascular disease, hypertension, and all-cause mortality.²⁻⁴ Despite the adverse health outcomes, physical inactivity and sedentary behavior have been determined as some of the priority health-risk behaviors in the college and university population.⁵ For instance, in 2014, about half (49.6%) of college and university students in the United States (US) reported insufficient daily aerobic physical activity participation for health as specified in physical activity guidelines.⁶ These data suggest a need for development of theory-based tools to reduce sedentary behaviors among the population.

The Transtheoretical Model (TTM) is an integrative model of intentional change regarding health behaviors that was developed from various theories of psychotherapy.⁷ This model has been applied successfully to a variety of health behaviors including smoking, substance abuse, alcohol use, depression, eating disorders and obesity, mammography, sunscreen use, exercise and physical activity.⁸⁻¹³ The TTM consists of 4 key constructs including stages of motivational readiness, processes of change, self-efficacy, and decisional balance. With respect to terminology, it has been recommended that stages of motivational readiness be used that emphasize both motivation for change and actual behavior change instead of stages of change.¹⁴

Stage of motivational readiness, a central construct of the TTM, represents a temporal dimension assuming people may progress cyclically through 5 stages when attempting to change their behaviors.¹⁵ The 5 stages are precontemplation (no intention to change behavior in next 6 months), contemplation (intention to change behavior within 6 months), preparation (temporary or irregular change), action (active involvement in changed behavior for less than 6 months), and maintenance (remained behavior change for more than 6 months). Because an individual's initial stage determines the content of the intervention strategies and progress through the stages is reflective of behavior change and intervention effectiveness,

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it is critical for measures to classify TTM stages correctly.¹⁶

Other key constructs of the TTM are used to describe how the changes occur. The processes of change are covert (cognitive) and overt (behavioral) strategies utilized to progress through the stages and can be classified into 2 representative processes: cognitive (ie, consciousness raising, dramatic relief, environmental reevaluation, self-evaluation, and social liberation) and behavioral (ie, contingency management, counter conditioning, helping relationships, self-liberation, and stimulus control).¹⁷ In general, the cognitive processes are used more frequently by those in the early stages, whereas people in later stages rely more on the behavioral processes.¹⁴

Self-efficacy refers to confidence in an individual's ability to perform specific behaviors in high-risk situations and not to relapse to the problem behavior.¹⁸ Self-efficacy has been considered one of the most important mediators to change health behaviors, and typically, people in later stages have greater scores of self-efficacy than those in earlier stages. Decisional balance indicates the individual's weighting of the perceived advantages and disadvantages of engaging in healthy or unhealthy behaviors.¹⁹ The TTM suggests that people will begin to perceive more advantages of behavior changes than disadvantages as they move through later stages.

The application of successful theories and models to reduce sedentary behaviors for specific populations is an emerging public health need. However, no one has applied the TTM to sedentary behavior. Based on numerous previous studies indicating the effectiveness of the TTM in changing various health-related behaviors, the TTM also might provide a useful and theoretical framework to address a prolonged sedentary behavior among college students.¹⁵ Therefore, the purpose of this study is to evaluate the measurement properties of the TTM questionnaire for sedentary behaviors among college students and to examine the validity and reliability of the developed TTM questionnaire.

METHODS

Participants and Protocol

A cross-sectional design was used to achieve the study purpose. With the instructor's permission, study staff members visited physical education courses, which were comprised of undergraduates representing various academic disciplines on campus, and encouraged the students to participate in the present study. Overall, 225 students aged 18 to 24 years were recruited from the physical education courses (N = 407) offered in the fall 2013 semester at the University of Texas at Austin. Participation was voluntary and anonymous. An informed consent form was collected to participate in the study.

After informed consent, participants received an activity monitor (eg, the ActiGraph GT3X+) with

written instructions including a link to an instructional YouTube video. Participants were asked to wear the device on their right hip for 7 consecutive days, during all waking hours of the day. After the 7-day data collection period, participants returned the monitors and were asked to complete the developed TTM questionnaires for sedentary behaviors. To assess test-retest reliability of the developed questionnaires, random subsamples of male (N = 49) and female (N = 59) students were asked to complete the same questionnaires again 2 weeks later.

Development of the TTM Questionnaire for Sedentary Behavior

Stages of motivational readiness to avoid sitting time. A Stages of Motivational Readiness questionnaire for sedentary behaviors was developed based on existing TTM measures for other behaviors.¹⁴ To avoid confusion for participants from varying definitions of sedentary behaviors, the term "sedentary behavior" was replaced with "sitting time" with the following definition: "any time outside of sleep during which you are sitting or reclining and experience less than 1.5 METs of physical activity including sitting, studying, watching TV, playing video games, using a computer, etc." and used interchangeably.¹ Stage of motivational readiness to avoid sitting time was assessed by a single question with a 5-item set of dichotomous (yes/no) or (true/false) response options. The 5 stages were characterized to classify participants into one of the 5 stages: Precontemplation (sitting most of the day and not intending to avoid sitting time), Contemplation (sitting most of the day but intending to avoid sitting time within 6 months), Preparation (sitting most of the day but intending to avoid sitting time within the next 30 days or sometimes do some movements such as interruption (break) of prolonged sitting to reduce sitting time), Action (not sitting most of the day and doing frequent movements purposely to interrupt or avoid prolonged sitting time within the last 6 months), and Maintenance (currently has small amount of sitting time and doing frequent and regular movements to avoid or break prolonged sitting time more than 6 months ago).

Other TTM constructs for avoiding sitting time. The questionnaires for processes of change, self-efficacy, and decisional balance were developed to assess a set of activities that could affect participants' sitting behaviors based on previously developed TTM questionnaires for other health-related behaviors.^{8,14,19} A questionnaire measuring processes of change was developed to identify the strategies and techniques people used to avoid sitting times. The questionnaire consisted of 40 items including a set of 4 core items measuring the frequency of use of 10 cognitive and behavioral processes with a 5-point Likert scale from 1 (never) to 5 (repeatedly). Self-efficacy scores were measured by using a 6-item situational confidence scale to

Table 1
Descriptive Demographics of Participants and Subsamples Used for Test-retest Reliability

Variable	Total Participants (N = 225)			Subsample (N = 108)		
	N (%)	Mean (SD)	Median (IQR)	N (%)	Mean (SD)	Median (IQR)
Age		20.4 (1.8)			20.8 (2.1)	
Sex						
Man	116 (51.6)			49 (45.4)		
Woman	109 (48.4)			59 (54.6)		
College Years						
1	10 (4.5)			4 (4)		
2	83 (36.9)			38 (35.1)		
3	68 (30.2)			34 (31.4)		
4	64 (28.4)			32 (29.5)		
Ethnicity						
White	81 (36)			38 (35.3)		
Hispanic	66 (29.3)			33 (30.5)		
African American	23 (10.2)			8 (7.4)		
Asian	55 (24.5)			29 (26.8)		
Sedentary Time (Min/Day)		493.5 (149.7)	486.4 (391.4, 570.9)		491.8 (145.3)	485.6 (392.1, 568.3)

Note.

N = number of participants; SD = standard deviation; IQR = inter-quartile range

avoid sedentary behaviors. Participants were asked how confident they are that they can avoid or break up (>1min) prolonged sitting time in 6 different situations that may lead them to be sedentary. An example of a situation is "When I am feeling tired." Each item was scored on a 5-point Likert scale from 1 (not at all confident) to 5 (extremely confident). Lastly, a decisional balance questionnaire was developed to assess how important each statement of pros and cons was with respect to the participant's decision of whether to avoid sitting time or not.^{20,21} The decisional balance scale consisted of 12 items including 6 pros and cons each for being sedentary with a 5-point Likert scale from 1 (not at all important) to 5 (extremely important). An example of a pro of avoiding sitting time is "Reducing sitting time would make me have a more positive outlook on life." An example of a con is "Reducing sitting time would make me tired for the rest of the day."

Measures

TTM questionnaires for sedentary behavior.

Four-core constructs of the TTM including Stages of Motivational Readiness, Processes of Change, Self-efficacy, and Decisional Balance were assessed to identify participant's motivational readiness to avoid sedentary behavior and to determine the factors influencing the behavior change.

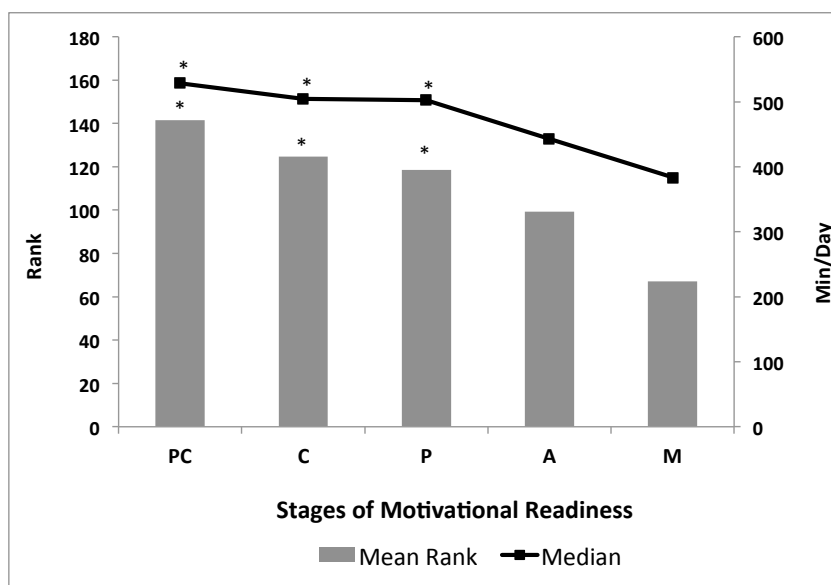
Accelerometers. Sitting time was measured ob-

jectively to validate the developed questionnaire of Stages of Motivational Readiness for sedentary behavior by using an accelerometer (ActiGraph GT3X+; Pensacola, FL). The ActiGraph GT3X+ accelerometer is a 4.6cm x 3.3cm x 1.5cm, triaxial piezoelectric activity monitor that measures acceleration from the vertical, horizontal and perpendicular axes. The data output from the device are activity counts, which quantify the amplitude and frequency of detected accelerations, and the activity counts are summed over a researcher-specified time interval (ie, epoch). For the current study, sitting time was recorded in 1-second epochs, and the data were screened for wear time by using the method requiring a minimum of 10 hours of wear time per day for at least 4 of 7 days.²² Briefly, device non-wear time was defined as 60 consecutive minutes of 0 counts, with an allowance for 1-2 minutes of detected counts between 0 and 100. Wear time was estimated by subtracting derived non-wear time from 24 hours.²² Total sitting time was calculated as the amount of time accumulated below 100 counts per minute during detected wear periods.¹ Technical specifications, as well as the validity and reliability of the ActiGraph accelerometer have been described previously.^{23,24}

Data Analysis

Descriptive statistics were computed for demo-

Figure 1
Mean Ranks and Medians of Sedentary Times across the Stages



* = $p < .05$

Note.

PC=precontemplation; C=contemplation; P=preparation; A=action; and M=maintenance

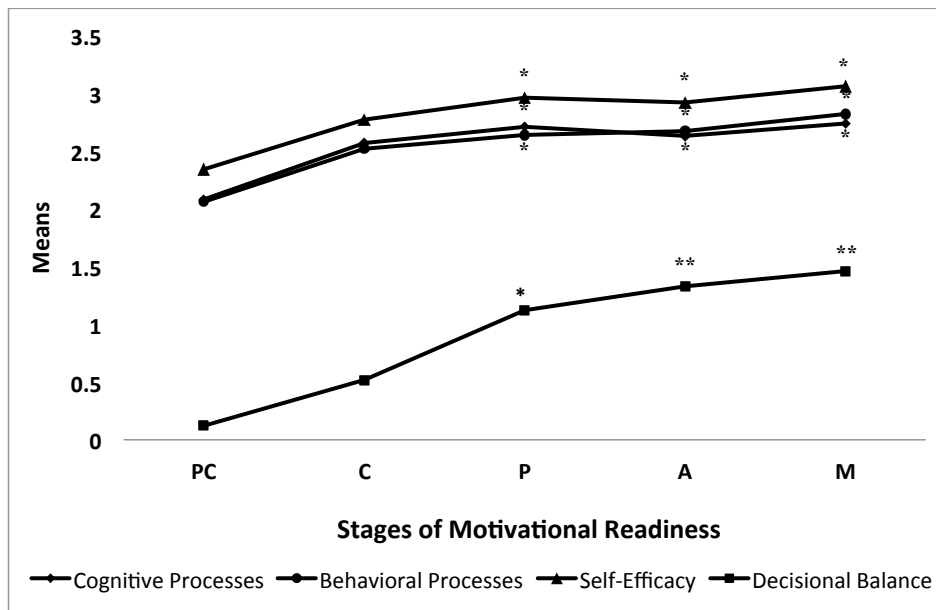
graphic variables and appropriate variables presented as means, standard deviations, frequencies, and percentages. All variables were assessed for normality with Shapiro-Wilk tests. To evaluate the concurrent validity of the TTM questionnaires, the differentiated stages were compared with accelerometer-derived estimates of sitting time. Because accelerometer-derived sitting time estimates were not normally distributed, both mean rank and median with inter-quartile ranges (IQRs) were generated for summary statistics. In addition, Jonckheere-Terpstra and Kruskal-Wallis tests were conducted for testing linear trends and mean rank differences across stages, respectively. Construct validity was evaluated by comparing mean differences in other TTM constructs between the stages. Multivariate analyses of variance (MANOVAs) with post hoc pairwise comparisons were conducted to determine mean differences in processes of change, self-efficacy, and decisional balance across stages of motivational readiness. Also, effect sizes (η_p^2) were generated to indicate the strength of association. For testing reliability, both internal consistency reliability and test-retest reliability, were examined. Cohen's kappa coefficient and Cronbach's alpha were calculated to test inter-rater agreement for categorical variable (stages of motivational readiness) and internal consistency reliability for continuous variables (other con-

structs), respectively. As a rule of thumb for values of Kappa, the following guidelines were used: moderate (.40 to .59), substantial (.60 to .79), and outstanding (above .8).²⁵ For Cronbach's alpha, comparable guidelines were acceptable (.7 to .8), good (.8 to .9), and excellent (above .9).²⁶ In addition, intra-class correlation coefficients (ICC) were calculated with a 2-way mixed model to estimate test-retest reliability. The present study followed the interpretation of test-retest reliability reported from Baumgartner et al: unacceptable (below .70), below-average acceptable (.70 to .79), average acceptable (.80 to .89), and above-average acceptable (above .90).²⁷ All calculations were conducted using IBM SPSS 20 for Windows.

RESULTS

Descriptive demographics of all of the participants and subsamples selected for conducting the 2-week test-retest are shown in Table 1. The mean age (\pm sd) was 20.4 (\pm 1.8) years, 48.4% of the participants were female students, and the average BMI was 23.7 (\pm 3.2) kg/m². Generally, the participants were evenly distributed among college years and ethnicity categories except for relatively low numbers of the first-year students and African-American students. The low proportion of African-American students in this study was, nevertheless, similar to its proportion (7.2%) for the entire un-

Figure 2
Mean Scores of the TTM Constructs across the Stages of Motivational Readiness Regarding Sedentary Behaviors



* = $p < .01$; ** = $p < .001$

Note.

PC=precontemplation; C=contemplation; P=preparation; A=action; and M=maintenance

dergraduate students at the university. The median sedentary time of the participants was 486.4 minutes/day. No statistically significant differences in sitting time were found among all demographical variables and between total and subsamples.

Concurrent Validity

Objectively measured mean ranks and medians of sitting time across the stages are presented in Table 2. The mean ranks of sitting time were significantly different across the stages ($\chi^2 = 25.0$, $p < .001$). The Jonckheere-Terpstra test for a non-parametric linear trend also showed significant differences between stages (JT = -4.512, $p < .001$). Participants in the stages of precontemplation, contemplation, and preparation had significantly higher amounts of sitting time than those in the maintenance stage ($p < .05$). The medians of sitting time tended to decrease across advancing stages.

Construct Validity

Mean scores of the TTM constructs used to verify the construct validity of the stages of motivational readiness are shown in Figure 2. In general, the mean scores for processes of change, self-efficacy, and decisional balance were significantly different across the stages ($p < .01$). Pairwise comparisons

for the significant findings in processes of change showed that participants in precontemplation had significantly lower scores on all of the behavioral and cognitive processes than those in preparation, action or/and maintenance ($p < .01$). No different patterns in using cognitive and behavioral processes were found across the stages. Overall, most of the mean scores of the processes were higher at higher stages. Similar patterns were found on the scores of self-efficacy and decisional balance. For example, participants in precontemplation reported they were significantly less confident in their ability to avoid sedentary behaviors in situations that encourage them to be sedentary than those in preparation, action, and maintenance ($p < .001$). Also, people in precontemplation were significantly less likely to perceive the advantages of avoiding sedentary behaviors compared to those in contemplation, preparation, action, and maintenance ($p < .001$).

The effect sizes showed that the greatest proportion of variance was derived from decisional balance ($\eta_p^2 = .16$), followed by counter conditioning ($\eta_p^2 = .14$), stimulus control ($\eta_p^2 = .13$), self-liberation ($\eta_p^2 = .12$), and self-efficacy and environmental reevaluation ($\eta_p^2 = .10$). The effect sizes of all of the TTM constructs were above medium effects ($\eta_p^2 = .06$), and the constructs were significantly associ-

Table 2
Summary of Internal Consistency Reliability and 2-week Test-retest Reliability of the TTM Scales

Construct	Cronbach's Alpha	95% CI	ICC	95% CI
Stages of Motivational Readiness	0.617 (Kappa value)	p < .001	0.94	[0.91, 0.97]
Processes of change				
Consciousness Raising	0.81	[0.73, 0.88]	0.85	[0.75, 0.91]
Dramatic Relief	0.81	[0.72, 0.88]	0.84	[0.73, 0.90]
Environmental Reevaluation	0.73	[0.60, 0.83]	0.82	[0.70, 0.89]
Self-Evaluation	0.80	[0.70, 0.87]	0.87	[0.79, 0.92]
Social Liberation	0.74	[0.61, 0.83]	0.80	[0.66, 0.88]
Contingency Management	0.82	[0.73, 0.88]	0.81	[0.68, 0.88]
Counter Conditioning	0.81	[0.72, 0.88]	0.84	[0.73, 0.90]
Helping Relationships	0.85	[0.78, 0.90]	0.85	[0.75, 0.91]
Self-Liberation	0.74	[0.61, 0.83]	0.76	[0.60, 0.86]
Stimulus Control	0.86	[0.79, 0.91]	0.84	[0.73, 0.90]
Self-Efficacy	0.75	[0.63, 0.83]	0.72	[0.54, 0.83]
Decisional Balance	0.76	[0.63, 0.83]	0.87	[0.78, 0.92]
Pros	0.87	[0.81, 0.91]	0.88	[0.80, 0.93]
Cons	0.73	[0.61, 0.81]	0.82	[0.70, 0.89]

Note.

CI = confidence interval; ICC = Intra-class correlation coefficients

Kappa value (p-value) was presented for the construct of stages of motivational readiness instead of Cronbach's alpha.

ated with the stages of motivational readiness.

Reliability

The internal consistency reliability and test-retest reliability were high for the developed TTM questionnaires with the random subsample (N = 108). There was no statistically significant difference in demographic variables between the total sample and subsample (p < .001) (Table 1). Regarding internal consistency reliability, a substantial inter-rater agreement (k = .62) on the stages of motivational readiness scale²⁵ and high internal consistencies ranging from acceptable to good on the scales of the other TTM constructs were obtained (Cronbach's alpha ranging from .73 to .87). In addition, intra-class correlation coefficients reported average acceptable test-retest reliabilities (ie, ranging from .80 to .94) on the entire scales of the developed TTM constructs except for 2: self-liberation ($\alpha = .76$) and self-efficacy ($\alpha = .72$), but were still acceptable. A detailed summary of the reliability tests is presented in Table 2.

DISCUSSION

The purpose of this study was to evaluate the measurement properties of the TTM questionnaire for sedentary behaviors among college students

and to examine the validity and reliability of the developed questionnaires. We saw strong evidence for the validity and reliability of the TTM questionnaires applied to objectively-measured sedentary behaviors. These results may support the ability of the stages of motivational readiness scale to categorize people into relevant stages in relation to their intentions to avoid sitting times and reveal the appropriate psychological strategies and techniques to progress through the stages. Overall, the findings may emphasize the potential of the TTM for successful application to sedentary behaviors and provide preliminary evidence of the TTM as a useful framework for future intervention research to reduce sedentary behaviors.

The questionnaire of stages of motivational readiness for sedentary behaviors demonstrated strong concurrent validity against objectively measured sitting time. The findings from the current study indicated that participants in the later stages had a lower amount of sitting time than those in earlier stages. The pairwise comparisons showed that the mean ranks and median of sitting time in the stages of precontemplation, contemplation, and preparation were significantly different from the scores in maintenance. In addition, additional significant differences were found in linear trend between

the stages of precontemplation and action by the Jonckheere-Terpstra test ($JT = -2.885, p < .05$). The statistically significant differences of daily sitting time across the stages suggest that the staging questionnaire is able to differentiate participants' intentions to avoid sitting times. The pattern of stage differences (ie, no significant stage differences between precontemplation and contemplation or between action and maintenance) support the findings of previous studies applying the TTM to other health behaviors (eg, smoking cessation and physical activity) that the differences between precontemplation and contemplation or between action and maintenance are not found in behavioral measures.^{25,28,29} This issue could be clarified by providing refined definitional criteria for each stage (ie, information about intensity, duration, or frequency) such as sedentary behavior guidelines.¹⁶

The construct validity of the developed questionnaires was demonstrated using the associations of core constructs of the TTM including processes of change, self-efficacy, and decisional balance with the stages of motivational readiness. Our findings indicate that participants used all of the 10 processes to avoid sedentary behaviors and both cognitive and behavioral processes were used more frequently in the later stages compared to earlier stages. An interesting finding of our study is the ascending patterns through the stages from precontemplation to maintenance in both cognitive and behavioral processes. This result supports previous studies indicating that individuals need to increase the use of all of the processes of change to move to later stages regarding exercise or physical activity.³⁰⁻³² In contrast, this finding also conflicts with others' previous studies indicating people in earlier stages (ie, precontemplation or contemplation) tend to use more cognitive processes than behavioral processes, whereas those in later stages (ie, preparation, action, or maintenance) show an inverse pattern.^{15,31} These controversial findings are not surprising because it is possible that the relationships between stages and processes of change vary depending on the applied behaviors.³² Our findings may suggest how the stages are differentiated by processes of change when the TTM is applied to sedentary behaviors as an independent behavior.

Similar to the processes of change, the scores of self-efficacy and decisional balance were higher in the advanced stages. The results suggest that the stages are able to be differentiated by the 2 constructs. For instance, individuals in precontemplation were less confident to avoid sitting time in the situations leading to become sedentary and perceived more disadvantages and less advantages of reducing sitting time compared to those in preparation, action, and maintenance. In addition, people in the action and maintenance stages perceived more advantages and fewer disadvantages by changing their sedentary behaviors compared to those in contemplation. Similar to these findings, most previous studies have shown high posi-

tive correlations between self-efficacy or decisional balance and the stages.^{15,31} These similar patterns provide evidence of the ability of the TTM to be applied to sedentary behaviors.

Lastly, the effect sizes of the constructs support the construct validity of these questionnaires. All of the core constructors had above medium effects based on Cohen's classification: small, medium, and large effects accounting for 1%, 6%, and 14% of the variance, respectively.³³ Particularly, decisional balance ($\eta_p^2 = .16$), counter conditioning ($\eta_p^2 = .14$), stimulus control ($\eta_p^2 = .13$), and self-liberation ($\eta_p^2 = .12$) had above or very close to large effects ($\eta_p^2 > .14$). These results suggest that the TTM can be a powerful and sensitive indicator to classify individuals into the 5 stages and to determine their process use and attitude variances in relation to sedentary behaviors.

Using relevant reliability measures, the questionnaires demonstrated a good inter-rater agreement ($k = .62$) on the staging scale and acceptable to good internal consistencies α ranging from .72 to .88) on the items of the other TTM constructs. Because the scale of stages of motivational readiness was a single-item measure and a categorical variable, a Kappa coefficient was used instead of Cronbach's alpha. In addition to the internal consistent reliability, most items of the scales demonstrated average acceptable test-retest reliability (ICCs ranging from .72 to .94). A 2-week interval was chosen for calculating test-retest reliability because this time frame (ie, at least 2 weeks) is usually recommended to avoid the effects of the first assessment. To the authors' knowledge, few studies have reported the reliability of the whole items of the TTM constructs when applied to various health behaviors. The scores in the current study indicate that the scales of the TTM constructs for sedentary behaviors have excellent reliabilities on internal consistency and test-retest. Therefore, the developed TTM questionnaires for sedentary behaviors are reliable.

The strengths of the present study include that it is the first attempt of developing a set of complete scales of the TTM constructs for sedentary behaviors. This validated tool may provide a theory-based framework and relevant strategies to reduce sedentary behaviors in future intervention studies. In addition, the current study provides the extended ability of the TTM for addressing another health-risk behavior (ie, sedentary behavior) and encourages health behavior specialists to apply the model for other populations to reduce their sedentary behaviors. Further, this study provides an objective measure of sitting time to validate the staging assessment for sedentary behaviors. The differentiated stages by the objectively-measured sitting time may help provide strong evidence of the concurrent validity of the questionnaires. Lastly, the use of various statistical tests for evaluating validity and reliability also may strengthen the results of this study.

Several limitations of the current study should be noted. The stage classification in the developed questionnaire solely relied on participants' intentions to avoid sedentary behaviors with a clear definition of sitting time. Possibly, this may confuse people and result in stage misclassification. There is a need of additional refinement on staging algorithms, and providing informational criterion (ie, a sedentary behavior guideline although it does not exist yet) may resolve this limitation. Also, our participants represented a convenience sample of college students. These results may not be generalizable to adults overall. Further research may be required with other populations to ensure the generalizability of the validity and reliability estimates. Finally, less-powerful non-parametric methods were used for analyzing some continuous variables which were not normally distributed. However, the use of various test and analyzing methods may address this limitation.

In summary, it appears that the TTM might be utilized to address sedentary behaviors to reduce college students' sitting times. The described high scores of validity and reliability of the developed scales suggest that the staging measure can assign college students to relevant stages regarding their intentions of avoiding sitting times and the other TTM constructs can provide appropriate techniques and strategies to avoid sedentary behaviors. Therefore, the TTM questionnaires for sedentary behaviors are acceptable to use for reducing sedentary times among college and university students and could be used to support a theory-based framework in future intervention studies.

Human Subjects Statement

The protocol was approved by the Institutional Review Board (IRB) of the University of Texas at Austin (approval document number 2013-08-0011). In accordance with the Federal Regulations the IRB reviewed the above referenced research study continuing review report and found it met the requirements for approval under the expedited category noted for the period of time of October 4, 2014 through October 3, 2015.

Conflict of Interest Statement

All authors of this article have no conflict of interest to declare in relation to this study.

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