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Readiness to Change in Rural Adults at High Risk for Diabetes

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READINESS TO CHANGE IN RURAL ADULTS AT HIGH RISK FOR DIABETES

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ABSTRACT

Type II diabetes is one of the most devastating chronic diseases in the United States and is associated with decreased lifespan and serious comorbidities. While evidence-based prevention strategies of nutrition and physical activity exist, behavior change is an essential component. Researchers use readiness to change to predict clinical outcomes of chronic disease prevention programs, however, this has not been well studied in rural populations. The purpose of this research was to study the relationship between readiness to change and attrition rates and clinical outcomes among rural dwellers enrolled in a nutrition and physical activity intervention. Article one of this three-article dissertation is a concept analysis, which resulted in an operational definition that readiness to change is the commitment and intention to engage in motivating cognitions and tasks necessary for sustainable behavior change leading to an expected outcome. This definition was used for tool validation and psychometric analyses in article two. Finally, the newly validated tool was used in article three to answer the primary questions of this research regarding the relationship between readiness to change and attrition and clinical outcomes. Results indicated that while readiness to change was not related to attrition nor did the stage of Readiness to Change predict attrition, the covariates of income and geography modified this relationship significantly. There was no significant relationship between readiness to change and weight, hemoglobin A1C, or blood glucose. However, a moderately strong effect size of 0.65 may indicate clinical significance in these results. This documents the need for future research with a larger sample size.

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Dedication

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Chapter 1: Introduction

Chronic diseases are putting significant strain on citizens of the United States both physically and financially. Chronic diseases, such as heart disease, diabetes, and cancer, are defined as lasting more than one year and are the greatest cause of disability and mortality in the nation (Centers for Disease Control and Prevention [CDC], 2019). Many chronic diseases are preceded by lifestyle behaviors such as tobacco use, a nutrient poor and calorie rich diet, lack of physical activity, and excessive alcohol use (CDC, 2019). Prevention and treatment hinge on changing these behaviors to modify disease risk and progression. This dissertation is a compendium of three articles which examined the relationship between behavior change and prediabetes outcomes in rural dwellers using the Transtheoretical Model of Change (TTM) framework.

Behavior change theories are utilized in many chronic disease prevention programs to guide interventions and assess impact on program outcomes. The TTM is one of those leading theories that was developed by Prochaska and DiClemente to combine components of over 300 psychotherapy models to better understand the process behavior change participants go through (Prochaska & DiClemente, 2013). This model asserts that everyone goes through a series of stages to make sustainable behavioral change, therefore stage of change is commonly assessed to determine how to tailor interventions to improve outcomes (Prochaska & DiClemente, 2013).

A commonality among these three articles is that readiness to change (RTC), which is used to measure stage of change associated with the TTM, is frequently used to predict behavior change outcomes. Readiness to change has demonstrated ability to predict outcomes across multiple

health disciplines, including chronic disease prevention, addiction recovery, and adherence to treatment protocols (Arvanitis et al., 2020; Ceccarini et al., 2015; Kaasalainen et al., 2016; Kullgren et al., 2015; Prochaska et al., 2015). However, there is a lack of consistency in the definition of RTC and ambiguity exists in its application and measurement. This has led to a plethora of tools that are developed to measure the RTC concept, however the published tools have several limitations. One limitation is that some tools lack a clear definition of RTC that guided their development, making it difficult to know what they are supposed to be measuring. A further limitation is that many of the RTC tools are designed with a specific population in mind, making it difficult to generalize them for use in other populations without establishing validity. Therefore, the three-article model was selected for this dissertation due to the clear fit of this model to this project. The first article presents a concept analysis of RTC that resulted in an operational definition based on a rigorous, evidence-based definition process. The second article describes an RTC tool validation study to establish validity and reliability of an RTC tool grounded in the operationalized definition established in article one. Finally, the third article explains findings from a study analyzing the relationship between RTC and clinical outcomes from start to month six of a program aimed at reducing the progression of prediabetes to diabetes in rural living adults in Montana.

Background

In 2016, the United States' spending on chronic disease treatment surpassed $1.1 trillion, which accounted for nearly 6% of the gross domestic product (Waters & Graf, 2018). Topping the list for the most expensive chronic diseases to treat is diabetes mellitus (Waters & Graf, 2018). Diabetes is characterized by high blood glucose that wreaks havoc on multiple bodily systems and leads to devastating complications such as cardiovascular disease, neuropathy,

retinopathy, and kidney failure, among others (Mayo Clinic, 2018). Type I diabetes is an autoimmune disease that develops when the insulin-making cells of the pancreas are attacked and stop producing insulin, while type II diabetes is characterized by cells becoming resistant to insulin's action in the body which results in a rise in blood glucose (Mayo Clinic, 2018). While there is no known prevention for type I diabetes, lifestyle is considered a modifiable risk factor to halt the development of type II diabetes (Mayo Clinic, 2018). While roughly 30 million people in the United States have diagnosed diabetes, of great concern are the over 84 million people who have prediabetes, many of whom do not realize they are prediabetic and are at great risk for developing type II diabetes in the next five years without intervention (CDC, 2019).

Prediabetes often presents with no symptoms; therefore, it is believed that nine out of ten people with prediabetes are unaware of their condition (Koenigsberg & Corliss, 2017). Prediabetes is diagnosed with fasting plasma glucose levels of 100 – 125 mg/dL, A1C of 5.7% – 6.4%, or a 75 gram, 2-hour oral glucose tolerance test with readings between 140 – 199 mg/dL (Koenigsberg & Corliss, 2017). There is a strong correlation between poor nutrition, lack of physical activity, and obesity, all of which are risk factors for the development of type II diabetes (American Diabetes Association, 2013). Proper nutrition and physical activity help keep blood glucose in a normal range, as well as help prevent obesity (American Diabetes Association, 2013) Therefore, current evidence-based practice places precedent on nutrition and physical activity in addition to modest weight loss as the key lifestyle prevention factors to stop the progression of prediabetes to type II diabetes (American Diabetes Association, 2013). However, it is evident that barriers to successful intervention still exist as diabetes diagnoses continue to rise at alarming rates (CDC, 2019). Therefore, there is an urgent need to further understand how to ameliorate this devastating and costly disease.

The National Diabetes Prevention Program (DPP) is a national evidence-based program that targets lifestyle changes among individuals with prediabetes with the goal of preventing its progression to type II diabetes and therefore, reduce its burden. The DPP is an intensive lifestyle intervention program that focuses on helping participants achieve a modest weight loss of 7% through a healthy nutrition and physical activity program (CDC, 2021). The National DPP is based on the large, multicenter clinical research study that showed substantial decrease in risk of type II diabetes for individuals who lost between 5-7% of their body weight through calorie reduction and at least 150 minutes of moderate intensity exercise each week (CDC, 2021). Individuals who lost the recommended weight had a staggering 58% lesser chance of developing type II diabetes than the control group, and after ten years of follow-up, these individuals still had one-third lesser chance of developing the disease (CDC, 2021). The National DPP, which is currently used across the United States, was born from this research and is still the accepted evidence-based, nationally recognized program to reduce the burden of type II diabetes. While the evidence clearly supports the benefits of this program, DPP program administrators in Montana have recognized varying success between participants. A less commonly discussed necessary thread to achieving successful outcomes in chronic disease prevention is sustainable behavior change, and research suggests that measuring behavior change can predict programmatic outcomes (Arvanitis et al., 2020; Ceccarini et al., 2015; Kaasalainen et al., 2016; Kullgren et al., 2015). Readiness to change is used as a measurement to classify behavior change participants into a stage of change based on the TTM developed by Prochaska and DiClemente (Prochaska et al., 2015), and this stage is then thought to be predictive of behavior change outcomes (Ceccarini et al., 2015; DiClemente et al., 2004; Peterson & Hughes, 2002).

Studies that examine RTC in relation to the DPP have indicated the importance of psychological predictors of behavior change, specifically components necessary to help individuals move through the TTM. What is not clear is the relationship between RTC and diabetes prevention outcomes in a rural population. Social determinants of health, or those conditions present in people's environments and lives that can influence their health, are important to consider (Thomas et al., 2014). It is recognized that one's environment and social context are important social determinants that can have an influence on behavior change (Kaasalainen et al., 2017; Kullgren et al., 2017; Thomas et al., 2014), but this has not been well studied in a rural population with pre-diabetes. Thomas and colleagues (2014) also discuss the importance of the health disparities that rural dwellers face. People that live in rural settings face what Thomas et al. (2014) call the triad of rural health disparities, which consist of culture, lack of economic opportunity, and geographic location. They suggested that even rural communities that face the same health problems will experience varying types of these disparities that influence health outcomes and emphasized the importance of understanding how these factors present themselves in specific populations. Several DPP studies that looked at rural and underserved populations indicated the importance of measuring RTC and placing participants in a stage to help better understand this concept, but as suggested by Thomas and colleagues (2014), the populations were very specific. The specificity of these studies makes generalization of results difficult, however, the research is still lacking on the relationship between a rural population and DPP outcomes. About 70% of the 1 million people in Montana live in rural areas and have a 13.4% poverty rate (Rural Health Information Hub, 2018), thus serve as a good study population for RTC and diabetes prevention.

The purpose of this research is to study the relationship between RTC and clinical outcomes among rural adults with prediabetes who are enrolled in a state DPP . There are multiple broader impacts of this work. First, having a clear operationalized definition of RTC can help chronic disease prevention efforts moving forward so researchers can more clearly articulate the relationship between RTC and their efforts. A further impact of this work will be broadening the understanding of how to tailor stage-based interventions for population in rural populations living with prediabetes. There are modifiable and preventative characteristics of many chronic diseases, including type II diabetes. However, understanding how behavior change works and how to facilitate progress towards change is paramount to understanding how to foster sustainable, long-term change to help individuals reap the anticipated health outcomes. Finally, reducing the burden of type II diabetes will greatly reduce the burden of chronic disease costs in the United States, and preventing the progression of prediabetes to full-blown type II diabetes is more cost effective than treating the disease and the associated comorbidities and complications (Waters & Graf, 2018).

Research questions

1) What is the relationship between RTC measured at baseline and attrition rates during a six-month health eating and activity intervention?
2) Is RTC predictive of clinical outcomes in rural adults living with prediabetes at six months into a healthy eating and physical activity intervention?
3) What factors mediate the relationship between RTC and clinical outcomes six months into a healthy eating and physical activity intervention?

Specific Aims and Hypotheses

Specific Aim 1. The first specific aim of this study was to determine the relationship between RTC and attrition rates in a nutrition and physical activity program delivered by the Montana DPP to rural adults with prediabetes. There are three hypotheses:

Hypothesis #1: It was hypothesized that higher RTC scores would be associated with lower attrition rates.

Hypothesis#2: It was hypothesized that dropout rate would be higher for individuals in the precontemplation stage than those in the contemplation and preparation stages of the TTM.

Hypothesis #3: It was hypothesized that lower income and rural geography would mediate the relationship between RTC and attrition rates unfavorably.

Specific Aim 2. The second specific aim was to determine the mediating effect of selected psychosocial factors on the relationship between RTC and clinical outcomes six months after initiation of a healthy eating and physical activity intervention. There are two hypotheses:

Hypothesis #1: It was hypothesized that of those who stayed in the program for the full six-month timeframe, those with greater baseline RTC scores would also have greater weight loss, and lower blood glucose and HbA1C at six-months.

Hypothesis #2: It was hypothesized that lower income and rural geography would affect the relationship between RTC and the clinical outcomes of weight loss, blood glucose, and HbA1C unfavorably.

Expected Outcomes

This research resulted in a developed operationalized definition of RTC to help alleviate some of the disparities in understanding this concept, as well as a better understanding of how RTC relates to clinical outcomes in a rural population living with prediabetes. This research will further the field of chronic disease prevention and offer new insights into the barriers and facilitators of sustainable behavior change for people with prediabetes living in a rural setting.

Significance and innovation

Scientific premise

Type II diabetes mellitus is a growing epidemic that significantly contributes to the burden of chronic disease in the United States (CDC, 2019). While effective diabetes treatments such as medications, nutrition, and physical activity exist, researchers acknowledge that taking a proactive approach of prevention is more beneficial than a reactive approach with treatment (CDC, 2021). Evidence-based prevention programs for people with prediabetes currently focus on the same treatment options for diabetics, namely physical activity and nutrition, however, there is a critical gap that is missing surrounding behavior change as it relates to adoption of diabetes prevention strategies in rural populations (Helitzer et al., 2007; Swan et al., 2007). By understanding how RTC relates to adoption of preventative behaviors, as well as facilitators and barriers to behavior adoption in a rural population, researchers can determine strategies to help people with prediabetes successfully reduce their diabetes risk stratification. This research is based on the hypotheses that people with prediabetes who are more ready to make a behavior change based on an RTC measurement will be less likely to be lost to follow-up and have improved clinical outcomes of HbA1C, fasting blood glucose, and weight.

Innovation

This study is innovative because it offers a different understanding of how RTC can influence behavior change as well as how RTC influences desired outcomes in a rural and medically underserved population. While RTC is well-studied in diabetes treatment and in specific subgroups, it is not well studied in a general rural setting. Once the relationship between RTC and the DPP in rural settings is better understood, future program efforts can be better tailored to meet individual needs to help participants not only persevere through the behavior change, but also reap the benefits of said behavior through improved health outcomes.

The last chapter of this compendium of articles, chapter 5, considers conclusions and future practice implications from this research, tying the chapters together. The practicality of utilizing RTC and the need for future research surrounding RTC in rural populations undergoing behavior change is discussed further. Chapter 5 is a further platform for discussion of the possible other covariates that should be included in future research that could affect people achieving their health related goals. Finally, chapter 5 presents the possibility of clinical significance in this study, which could be important for individuals even if not statistically significant.

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Chapter 2: Concept Analysis of Readiness to Change

Abstract

Readiness to change is a construct used in numerous settings and is particularly relevant in health behavior change. An individual's level of readiness to change has been used to predict behavior change outcomes in countless settings from addiction treatment to weight loss and chronic disease prevention and treatment programs; however, its ubiquitous application has led to confusion surrounding its utility. The Rodger's Model of Concept Analyses was utilized to develop an operationalized definition of readiness to change for use as a metric in diabetes prevention research in rural Montana. This systematic approach resulted in an operationalized definition that states that readiness to change is the commitment and intention to engage in motivating cognitions and tasks necessary for sustainable behavior change leading to an expected outcome. This concept analysis elucidates the interconnectedness between readiness to change and multiple other concepts while helping to clarify the evolving nature of behavior change.

Keywords: Readiness to change; behavior change; motivation; engagement

Article 1: Concept Analysis of Readiness to Change

The construct of Readiness to Change (RTC) is frequently used in a myriad of behavioral change settings, particularly in weight loss, exercise programs, addiction, and tobacco cessation programs, as well as other chronic disease prevention programs (Arvanitis et al., 2020; Ceccarini et al., 2015; Kaasalainen et al., 2016; Kullgren et al., 2017; Prochaska et al., 2015). From health behavior change to organizational and managerial change (Matthysen & Harris, 2018), RTC can help researchers better understand the change processes people undergo. The construct of RTC is derived from the Transtheoretical Model of Change (TTM) developed by Prochaska and DiClemente in the late 1970s. At the time of development, there were over 300 theories in the fields of psychotherapy and behavior change, so the TTM was developed to integrate components of these theories into a unified theory to explain behavior change (Prochaska et al., 2015). The TTM is comprised of the stages of change, processes of change, self-efficacy, temptation, and the decisional balance of making a change (Prochaska et al., 2015). While the TTM has been applied to many populations and expanded upon by other researchers, the core of the TTM is unchanged, allowing for broad application (Prochaska et al., 2015). Prochaska and colleagues (2015) asserted that there are critical assumptions of the TTM that must be considered: There is no behavioral change theory that fits all circumstances, behavioral change is temporal, stages of change can be fixed or open to change, most people engaging in behavior change are not in the action stage, and processes of change should be employed between different stages to help individuals move through the stages.

Readiness to Change is used alongside the TTM in research to try to predict behavioral change participant outcomes. DiClemente et al. (2004) indicated that RTC has been associated with the stages of change from the TTM to provide greater individual support to behavior change

participants; therefore, the TTM is the theoretical framework that guides measurement of RTC. Despite the TTM consisting of multiple parts, many studies solely use the stages of change as a measure of RTC with no mention of the other parts of the TTM as the predictor of outcomes; however, DiClemente et al. (2004) are clear that the processes of change help a person move through the stages. A study by LaPlante-Levesque et al. (2013) asserted that the stages of change should be depicted as more of a continuum of change as opposed to staging since people can go back and forth between stages (LaPlante-Levesque et al., 2013). Further, a study by Vallis et al. (2003) used the stage of change of participants as the measure of RTC itself for incorporating healthy eating into a diabetes management program and used the stage of change as a predictor of how well participants would adhere to prescribed diet interventions and associated clinical outcomes. However, this contradicts the research by Sarkin et al. (2001), which states that the stage into which a participant is classified is indicative of their level of readiness, not necessarily the outcome itself. Additional studies similarly use stages of change as a measure of RTC without discussion of facilitators and barriers to change (Eckhardt & Utschig, 2007; Helitzer et al., 2007; Ingo et al., 2016), indicating the vague nature and the interchangeability, whether appropriate or not, of the uses of the TTM, stages of change, and RTC across different health applications.

A multitude of similar terms are used in the RTC literature, including, but not limited to motivation, activation, engagement, empowerment, health belief, willingness, self-efficacy, decisional balance, confidence, interest, commitment, and intention. DiClemente and colleagues (2004), the developers of the TTM and the concept of RTC defined RTC, stating that RTC is "a patient's perceived importance of the problem and confidence in his or her ability to change." They also indicated that RTC is one's willingness to commit to changing their behavior with a

specific change process and necessitates a level of motivation that implies preparation for said change (DiClemente et al., 2004). While DiClemente and colleagues (2004) provide this definition of RTC, the loose application of RTC in recent years has led to confusion of its application. Therefore, the purpose of this concept analysis is to develop an operationalized definition of RTC and add new understanding by examining how it has evolved over time. Clarification of the meaning of RTC will help researchers within the same disciplines and across different disciplines more clearly understand and communicate findings related to behavior change so they can work more effectively to help foster change. To achieve this purpose, a systematic analysis of the attributes of RTC was conducted. The result of this literature review was an operational definition of RTC that includes the necessary attributes used in scholarly work to use in future behavior change programs and research.

Methods

The Rodger's model of concept analyses offers a systematic approach while recognizing the progression of a concept over time and allows for situational context to be accounted for (Ng & Luk, 2019). This model was chosen over others for several reasons, including the evolving understanding of RTC, the temporal element that indicates that RTC itself changes over time based on individual context, and the use of inductive reasoning to establish the operational definition (Kaasalainen et al., 2016; Peterson & Hughes, 2002).

Data Sources

The objective of the search strategy for RTC articles was to find an appropriate and reliable sample of articles that was representative of the concept. There are many terms used that share similarities with RTC, thus the search strategy diverged from solely using search strings and included manual article searches. The databases used for this search were CINAHL,

PubMed, PLOS, and Google Scholar. The searches were limited to articles written in English and published since the year 2000. The initial search strategy included the MeSH terms "Transtheoretical Model of Change" AND "Readiness for Change," OR "Readiness to Change." The ability to find a clear description of RTC in the literature was hindered by inconsistencies in the use of the term, thus an exploration of terms used in behavior change literature that were being used interchangeably with RTC were explored, resulting in a revised search strategy. It was noted that authors were commonly using the terms "stages of change," "activation," "motivation," and "engagement" to describe RTC, so an RTC search that included these terms with the Boolean operator "OR" was conducted.

The search string for this was: "Transtheoretical Model of Change" AND "Readiness to Change" OR "stages of change" OR activation" OR "motivation" OR "engagement." This search resulted in a greater breadth of articles that utilized concepts related to RTC with 118 articles after inclusion and exclusion criteria were applied. Another search included the following search string: "Stages of change" AND "Readiness to Change" AND "Diabetes Prevention." This search resulted in three additional articles.

Articles for this concept analysis were also obtained from using the related articles discovered in the database searchers. To find related articles, the related articles function and the reference lists of relevant articles were scanned for articles that may have been useful in describing the phenomenon of RTC. The article selection process can be viewed in **Figure 1.** Additionally, if multiple articles on the same topic existed, the original article that formed the basis for all others was used. Narrowing the search to the original articles on a topic resulted in a clear sample of articles on this concept. The construct of RTC is used across multiple fields of study; however, this concept analysis only includes articles used in health behavior.

Quality Assessment

The quality of articles was assessed with initial inclusion criteria set that articles must contain a definition of RTC. This proved difficult as many articles only reference RTC with no definition given, thus greatly limiting the number of articles available to select from. Therefore, articles that included any reference to how RTC was defined were included in the analysis. These articles often did not identify that they were defining RTC but used terminology regarding characteristics of RTC, which was considered a definition for the purposes of this concept analysis. The next step for assessing article quality was to include articles that included critical attributes of RTC. However, only a couple of articles with definitions had critical attributes of RTC clearly defined, so all articles with definitions as noted in the first inclusion round as well as the articles with the critical attributes were included in the analysis.

Data Selection Process and Analysis

Due to the use of multiple terms that are similar to RTC in the literature, related terms were identified and included in the database searches and included in the selection of articles for analysis. Articles were then categorized based on the related term used. The major categories of related terms were stages of change, motivation, activation, and engagement. Articles in these categories were then evaluated for similarities and differences in definition and critical attributes if they were present. Once articles were selected, they were compared and contrasted to develop the operational definition of RTC. Some of these articles discussed triggers for improved RTC, so a section on this was also included in the analysis as triggers are an important component of this construct.

Results

Surrogate Terms and Related Concepts

Surrogate terms were identified prior to beginning the article search due to inconsistencies in the use of terminology around RTC. After a personal phone interview with Dr. DiClemente, it was determined that there are no true surrogate terms that encompass all of RTC; however, there are multiple related concepts that aim to portray the same idea and are included in the definition (C. DiClemente, personal communication, August 6, 2020). These include motivation and engagement. Examples of terms that were frequently used as surrogates in the literature can be viewed in **Table 1.**

Attributes

The attributes of a concept are the critical components that are present across the reviewed literature once taken into context of the concept (Ng & Luk, 2019). From this analysis, there are closely related attributes of RTC: stages of change, motivation, activation, and engagement. Ceccarini et al. (2015) indicate that classifying a person within a certain stage of change from the TTM is how RTC is measured, thus the TTM serves as the theoretical framework for RTC. This denotes that using the term stages of change is appropriate in the context of measuring RTC as this is what the stages of change appear to be measuring. Determining how ready a participant is to make a change appears to be the application of the stages of change in health behavior literature (Prochaska & DiClemente, 2013).

Motivation

Motivation can be defined as the reasons people act a certain way or the willingness for a person to do something (Merriam-Webster, 2005). DiClemente et al. (2004), assert that

motivation is the defining attribute of RTC. Motivation is utilized in the descriptions of both the TTM and RTC across the literature.

To begin, DiClemente et al. (2004) gave a clear definition of motivation and said that motivation is often what researchers are trying to understand when measuring RTC. Their definition of motivation "refers to the personal consideration, commitments, reasons, and intentions that move individuals to perform certain behaviors (DiClemente et al., 2004)." Further, they say that any intentional behavior change must have underlying motivation (DiClemente et al., 2004). Ingo et al. (2016) used the term motivation in the title of their article, indicating that they are using the TTM to measure levels of motivation. They also go on to say that measuring RTC is an important aspect of their study and that RTC enhances their patients' abilities to enter and successfully participate in rehabilitation for audiologic disorders (Ingo et al., 2016). They indicate that seeking help and starting rehabilitation show behavior change in their population (Ingo et al., 2016) and that the stages of change would be used. Beyond this, there is no further mention of the terms RTC or motivation; however, they do use the stages of change to try to predict patient outcomes.

A study by Kaasalainen et al. (2016) on increasing physical activity in Finnish men utilized the TTM as the framework to understand behavior change to increase physical activity and improve eating behaviors. Kaasalainen et al. (2016) use the terms RTC and motivation in their descriptions of the TTM, specifically using the term "motivational readiness to change," which is consistent with the use by DiClemente and colleagues (2004), who developed the TTM. They further describe each stage of change as the next motivational stage and that motivation is what helps people move through the stages and achieve behavioral change (Kaasalainen et al., 2016). They emphasize that motivation is what predicts a strong commitment to continue

behavioral change (Kaasalainen et al., 2016). Kaasalainen et al. (2016), while not defining RTC itself, made the clearest distinction of RTC as being defined by motivation. Kaasalainen et al. (2016) also describe the relationship of the term intention to behavior change, stating that intention is a willingness to work hard at something. Intention and motivation are used synonymously here since both have willingness as a defining attribute.

An earlier study by Peterson and Hughes (2002) on RTC in a diabetes education program uses the terms readiness and willingness synonymously, using both to define how they use RTC in their study. Willingness, as mentioned above, is in the definition of motivation. Peterson and Hughes (2002) do not use the term motivation directly but refer to the stages of change from the TTM as the stages of RTC and assert the importance of readiness or willingness in effective behavioral change. They state that willingness increases as participants move through the stages in the TTM, reinforcing the behavioral changes being made (Peterson & Hughes, 2002). Research by Ceccarini et al. (2015) further corroborates the notion that motivation and RTC can be used interchangeably as they consistently discuss them synonymously in their research. Critchley et al. (2012) also use the term of motivation to change when referring to the TTM, indicating that their definition of the stages of change includes the term motivation. Another interpretation of the relationship between motivation and RTC is that by enhancing motivation, RTC is in turn enhanced, suggesting that they are not one and the same but are intricately related (Eshah, 2019). Finally, DiClemente and colleagues (2004) discuss RTC and motivation interchangeably, citing that many researchers use the stages of change to measure motivation as a model for understanding behavior change.

Activation

A concept that is like RTC and sometimes used interchangeably in the literature is the term activation. Patient activation is related to improved outcomes across a myriad of health outcomes (Ancker et al., 2015). Hibbard et al. (2007) defined activation as a patient's knowledge, skills, and confidence to work towards behavior change, which expands on Wagner's definition from the Chronic Care Model of an individual's willingness and ability to engage in health behavior change and to manage their health (Wagner et al., 2001). This use of the definition is corroborated by a study by Eyles et al. (2020) that utilized the Patient Activation Measure (PAM), developed by Hibbard and colleagues, to study osteoarthritis self-management. Ancker et al. (2015) included the importance of motivation for improving health outcomes by including it in their discussion about patient activation; however, they did not state it in their definition of activation itself. Conversely, Arvanitis et al. (2020), who sought out to develop a new instrument to measure influence, motivation, and activation in patients with diabetes, add to the definition of activation to include motivation as a descriptor. In multiple places throughout their article, they use the terms activation and motivation synonymously, referring to activation in parentheses when they used the term motivation, which seems to be a departure from the definition of activation according to the developers of the PAM. They developed a working definition of patient activation for their research, citing that activation is "the degree to which patients value health and believe they can influence it." Arvanitis and colleagues (2020) further explained the relationship of health literacy, or one's knowledge and skills on their health condition, as an important correlate with patient activation.

If one sticks with the definition of patient activation from Hibbard et al. (2017), who developed the PAM, then activation is similar in nature to several other concepts under the umbrella of motivation and includes triggers such as self-efficacy and health literacy, which indicates its similarity to RTC. Based on the definitions provided of RTC from DiClemente et al. (2004) and of patient activation from Hibbard et al. (2017), activation can interact with RTC, but these concepts are not one and the same.

Engagement

Another term that consistently shows up in RTC literature is engagement. Yet another vague term in behavior change literature, patient engagement has been used synonymously with patient activation and commitment. A study by Samra et al. (2015) gave a clear definition of parental engagement as they developed an instrument to measure engagement levels among parents of premature infants. They defined engagement as active participation in care and decisions that also took parental skills, knowledge, and values into consideration. They noted that engagement is about goal-oriented behavior. Another study by Kullgren et al. (2017) on diabetes prevention defined conditions that must be met for a patient to engage in behavior change. They stated that the patients must believe they have an elevated risk for the disease, have the motivation to change, have knowledge of strategies to change behavior, and have self-efficacy to complete the behavior change (Kullgren et al., 2016). Like Samra et al. (2015), Kullgren et al. (2016) also discussed the importance of goal-oriented behavior as an important component of patient engagement. The similarities between Samra et al. (2015) and Kullgren et al. (2016) further advance the understanding of patient engagement. DiClemente and colleagues (2004) further corroborate the idea of the importance of intent to engage in part of their definition of RTC, stating that RTC infers a willingness to engage. Engagement is a dynamic

concept that includes the health belief, motivation, and self-efficacy to participate in goal-directed behavior, including completing the cognitive tasks necessary to move forward in the stages of change. DiClemente et al. (2004) indicate that motivation is necessary to complete the tasks associated with each stage, so if one views engagement as performing the activities associated with the stages necessary to achieve goal-directed behavior, then engagement is a necessary component for one to move through behavior change.

These studies had the clearest definition of engagement, which is a relatively new concept in the health field. It is noted that while patient motivation is an important part of engagement, motivation and engagement are not the same, and rather, motivation is necessary for a patient to engage in behavior change. Based on the personal interview with DiClemente (C. DiClemente, personal communication, August 6, 2020), engagement does not fully encompass what RTC is measuring, as one can be engaged in different stages of change without actually making a behavior change. However, if one looks at how engagement is used in the literature since the development of the TTM, it appears that it is a robust and dynamic concept that includes components of motivation, activation, and readiness to help an individual move through the stages of change and conveys the same ideas as RTC.

Antecedents for RTC

A theme that is consistently present in RTC research is the importance of triggers for behavior change. One's health belief, which includes perceived personal risk, perceived need for change, and perceived benefits of change, is an important trigger for participants to change their health behaviors (Kaasalainen et al., 2016). Kullgren et al. (2016) also discuss the importance of the participant's health belief and perceived risk of developing a disease to initiate behavior change. This health belief is a necessary component to decisional balance in the TTM, indicating

one must perceive a problem to make the decision to change. Kaasalainen et al. (2016) describe the perceived benefits of behavior change as crucial to a person adopting said change, while motivation is a measurement of commitment to these changes. Further, the use of the term health literacy is used to help inform one's health belief and can prompt a participant's commitment to action (Arvanitis et al., 2020). Specifically, one's perceived risk for developing a disease is commonly mentioned as a facilitator of motivation to change behavior (Kaasalainen et al. 2016). Self-efficacy, which is one's belief that he/she can do a specific task (Prochaska & DiClemente, 2005), is important for behavior change in the TTM (Kaasalainen et al., 2016). Some studies refer to self-efficacy and confidence in specific abilities interchangeably, but regardless, it is clear that one's belief in their abilities is an important factor in the decision to pursue behavioral change. Research by William and Rollnick (2012) indicates that self-efficacy enhances one's motivation to make change, and research by Kullgren et al. (2017) indicates the importance of self-efficacy to persevere with behavior change.

Consequences

The consequences are the application of the concept in real life (Ng & Luk, 2019). Ceccarini et al. (2015) assert that it is imperative that RTC is measured for any researcher wanting to understand change. The notion is that RTC is predictive of outcomes and measuring RTC early on can help researchers tailor intervention strategies to individuals based on the stage of change they are in from RTC measurements.

Discussion

For the purposes of this concept analysis, the operationalized definition of RTC is the commitment and intention to engage in motivating cognitions and tasks necessary for sustainable behavior change leading to an expected outcome. Upon analysis, it is clear that motivation is imperative to the understanding of RTC, and engagement, when taken as goal-oriented action, requires the self-efficacy, health belief, and skills to perform the cognitive tasks to make a change. Each stage of change associated with the TTM has specific cognitive and behavioral tasks that the individual must complete to move forward in the behavior change and requires the individual to modify or stop problematic behaviors and adopt new behaviors (DiClemente, 2007). DiClemente (2007) indicates that motivation cannot be sporadic, but one must have committed to the behavior change to remain motivated to adequately complete the necessary tasks associated with the change. These tasks then build on one another until the desired behavior change is achieved and becomes habitual to result in the desired outcome. Therefore, this operational definition aligns with developers of the TTM and expands upon it by clarifying how engagement is related. It helps further the understanding of RTC by indicating that motivation is the "why" and engagement is the "how" behind intentional behavioral change.

Personal communication with Dr. DiClemente (August 6, 2020) indicated that engagement should not be interchanged with RTC as one could be engaged but not make progress towards sustainable behavior change. However, if one looks at engagement as persisting towards goal-directed behavior, then engagement seems to be an appropriate way to conceptualize how one moves through the stages of change associated with the TTM. When considering DiClemente's (personal communication, August 6, 2020) definition of RTC, individuals must have the motivation and be committed to change their behavior, as well as take

the necessary action towards behavior change. Used in this context, engagement is a robust term that includes motivation, activation, and readiness as well as the actual participation in behavior change activities (Samra et al., 2015; Kullgren et al., 2017).

While not included in the operationalized definition, activation, defined as a patient's knowledge, skills, and confidence to work towards behavior change (Hibbard et al., 2017), incorporates similar components to RTC, but specifically includes the skills necessary for people to complete the behavior change. DiClemente (personal communication, August 6, 2020) suggested that RTC necessitates that a person is ready to take on the tasks associated with the stages of change, so having the skills to perform these tasks is important. If one examines the definition by Hibbard et al. (2017), knowledge and health literacy are similar, and confidence is similar to self-efficacy. It is logical that someone who understands their health condition and has confidence and skills to make changes would be better equipped to perform the action of decisional balance, a necessary component of RTC. Furthermore, it appears that both RTC and activation serve the purpose of helping people move forward with making behavior change. However, for this definition, engagement encompasses the key components of activation; therefore, activation was not included in the definition.

As research on behavior change has evolved, it is apparent that confusion exists around RTC and the similar concepts of motivation, activation, and engagement that are often treated as surrogates for the concept. As DiClemente (personal communication, August 6, 2020) suggested, RTC allows flexibility for some interpretation by the researcher. While these concepts are in the literature surrounding RTC and some are contained within the operationalized definition of RTC for this concept analysis, the ubiquitous use of these terms highlights the overlap in behavior

change literature. Including motivation, confidence, and engagement (which encompasses activation) into one's understanding of RTC offers a more robust way to view behavior change.

Conclusion

For behavioral change to occur, the person must hold the health belief that they are susceptible to illness (decisional balance) have (1) sustained level of motivation intensity (encompasses willingness and intention to change), (2) self-efficacy or confidence in one's ability to make a change, and (3) sustained engagement in goal oriented behaviors that lead to an expected outcome (encompasses acquisition of new behaviors, skills and knowledge, which in turn leads to increased self-efficacy and motivation). Paired with self-efficacy, skills, confidence, and health literacy or knowledge, the individual will be triggered and motivated to engage in the necessary behavior change. Much like the TTM spans many models of psychotherapy and behavior change, RTC is closely related to several concepts that have been studied more closely since the TTM was developed and became popular. The construct of RTC has fluidity that allows for researchers to adapt the model to help explain phenomena, and this operationalized definition adds engagement to help explain phenomena for this research.

Moving forward, researchers investigating RTC and behavioral change should also include motivation, activation, and engagement in their literature searches to capture a bigger picture of the behavior change literature due to the interplay between these concepts. These are components of RTC that a researcher should consider capturing within the concept, so not including engagement in the operationalized definition, and therefore, not on the tools used to measure RTC, means not all the stages of the TTM are being captured. Future research should consider if these components operate independently or if they all do work together under the main concept of RTC. However, for the purposes of this concept analysis, they are included

under the main operationalized definition of RTC and all contribute to the measurement of ta single measure which may have one or more components. They are intricately linked and can add to the understanding of one another. While applications of the TTM vary across behavior change literature, the core of the TTM and RTC remain unchanged, and this operational definition just helps make sense of how newer terms in behavioral change interact and may be measured.

Practice Implications

This concept analysis elucidates the interconnectedness between RTC and similar concepts while helping to clarify the evolving nature of behavior change. This operationalized definition of RTC served as the metric which an RTC tool used in the Montana Diabetes Prevention Program was evaluated against. For the purposes of that study, the Montana DPP instrument should measure the main concepts of motivation, confidence, and engagement. Triggers of health belief, self-efficacy, knowledge, and skills should also be included on the tool. Other tools used to measure RTC should undergo validity testing to ensure they measure the main concepts associated with RTC as defined in this concept analysis. Once accurately measured, RTC can be used to help predict outcomes and help practitioners provide targeted strategies to individuals wishing to make lasting change.

Research Implications

This concept analysis also has implications for future research in health behavior change. There was a plethora of information about RTC when the literature review was conducted for this study, which resulted in confusion on the concept's utility. With an operational definition, researchers can focus their efforts on including research that directly aligns with the definition to narrow the scope of their literature searches. Further, this knowledge will enable researchers to

be certain that what they include in their RTC measurements and clinical predictions aligns with a definition that was developed in a rigorous and systematic process.

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Figures and Tables

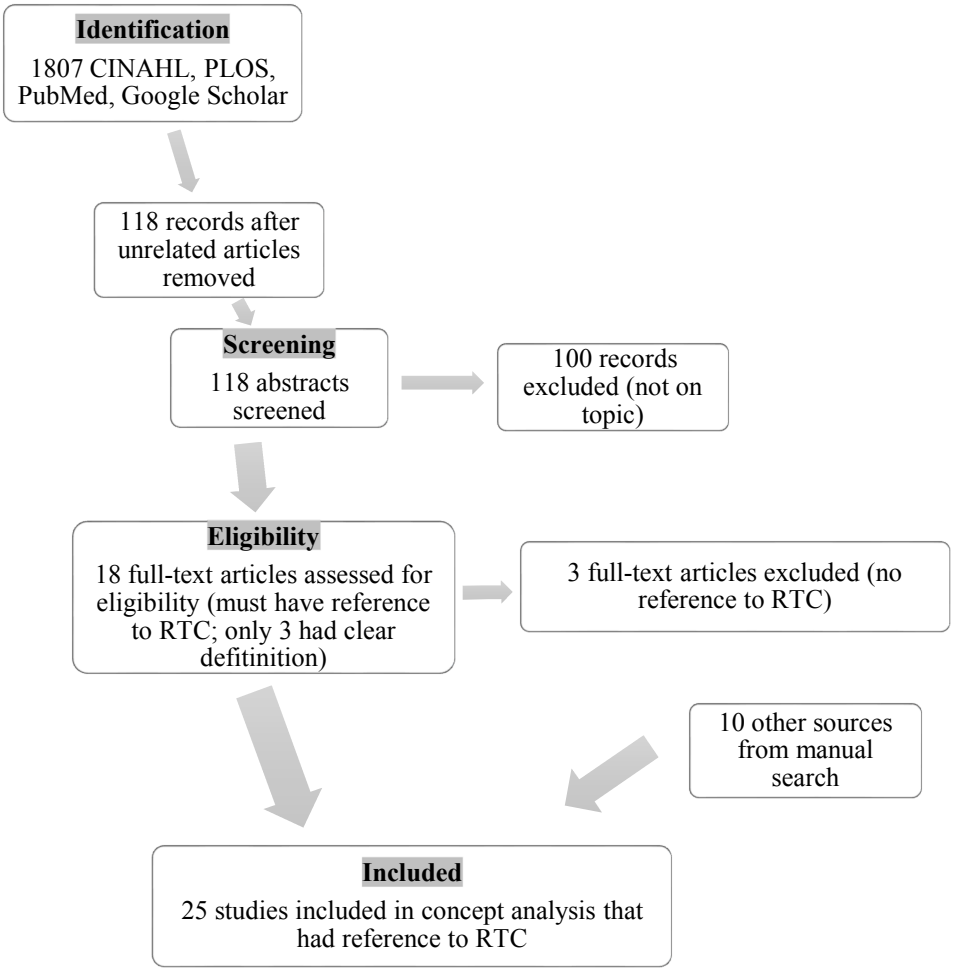

Figure 1: Diagram of Article Selection Process

Table 1: Examples of Terminology Related to RTC

Authors	Synonyms used for RTC	Related Concepts	Defining Attributes
Arvanitis, M., Bailey, S. C., Wismer, G., Griffith, J. W., Freeman, E., Sims, T. J., ... & Wolf, M. S. (2020).	Activation; Influence; Motivation	Stages of change; Health Belief Model	Motivation and activation used synonymously
Ceccarini, M., Borrello, M., Pietrabissa, G., Manzoni, G. M., & Castelnuovo, G. (2015).	Motivation	Stages of change	Motivation is interchangeable with RTC to move a person through stages of change
Eckhardt, C. I., & Utschig, A. C. (2007).	Stages of change; Motivation	Transtheoretical Model of Change	Predictive ability of stages of change
Ingo, E., Brännström, K. J., Andersson, G., Lunner, T., & Laplante-Lévesque, A. (2016).	Motivation	Transtheoretical Model of Change; stages of change	Enhanced ability to be successful at behavior change through motivation to go through stages of change
Kaasalainen, K. S., Kasila, K., Komulainen, J., Malvela, M., & Poskiparta, M. (2016).	Motivation; motivational readiness to change; commitment	Stages of change; Transtheoretical Model of Change	Motivation provides the catalyst to move through stages of change
Kullgren, J. T., Youles, B., Shetty, S., Richardson, C., Fagerlin, A., & Heisler, M. (2017).	Engagement; motivation	Health Belief Model; Self-efficacy	In order to engage, participant must first have motivation; goal-directed behavior
Samra, H. A., McGrath, J. M., Fischer, S., Schumacher, B., Dutcher, J., & Hansen, J. (2015).	Engagement; Patient Engagement	Skills; knowledge; values	Engagement implies goal-directed action

Chapter 3: Validation of the RTC Tool

Abstract

Readiness to change is commonly measured to help researchers predict clinical outcomes in behavior change science. Understanding one's readiness to change score can help researchers deliver stage-matched interventions to help individuals be more successful in achieving their health-related goals. A perplexing number of readiness to change tools exist, however, many are of unknown origin, lack development from a rigorous scientific process, or are adapted from addiction studies, making it difficult to apply them to other areas. Weight loss lies at the foundation of many chronic disease prevention programs, however, there's a lack of readiness to change tools that specifically measure behavior changes necessary to weight loss. The purpose of this study was to determine the content validity, reliability, and psychometric properties of an existing readiness to change tool for use in a rural population participating in the Montana Diabetes Prevention Program. Schilling's model for content validity was used to determine content validity, and Cronbach's alpha coefficients were used to determine reliability of the tool. These methods resulted in a modified tool that was then piloted in a development sample of 38 participants enrolled in a Diabetes Prevention Program. The same psychometrics analyses were run on the newly modified tool, and it was determined that it provides a valid and reliable measure of readiness to change in rural populations living with prediabetes.

Keywords: Readiness to change; readiness to change tool; validity; reliability

Article 2: Validation of the RTC Tool

Human behavior change is complex and active area of research in chronic health condition prevention and treatment. While knowledge alone is insufficient for most people to change problematic behaviors, readiness to change (RTC) offers researchers a promising way to measure and better understand how to help individuals persist with lifestyle change (Ceccarini et al., 2015). The concept of RTC is an application of the transtheoretical model of change (TTM) originally developed by Prochaska and DiClimente in the mid-1970s (Prochaska et al., 2013). Readiness to change tools followed suit to help predict individuals who would be successful in overcoming addiction (Prochaska et al., 2013), so many of the existing tools have been adapted from addiction studies (Ceccerini et al., 2015). Today, RTC is utilized in a myriad of settings from organizational change to health behavior change. In health behavior, the intent in measuring RTC is to determine if clinical health outcomes can be predicted early in behavioral change programs based on an individual's RTC level, then use this information to better personalize behavior change strategies.

A literature review revealed a large number of RTC tools; however, research does suggest that RTC levels measured by some of the existing tools have established predictive ability of outcomes across a variety of health settings (Arvanitis et al., 2020; Ceccarini et al., 2015; Kaasalainen et al., 2016; Kullgren et al., 2015; Prochaska et al., 2015). The University of Rhode Island Change Inventory (URICA) and the Decisional Balance Inventory (DBI) are two commonly used RTC tools that are valid, reliable, and have good psychometric properties (Ceccarini et al., 2015; Keawwhan et al., 2016). However, the URICA offers a broad perspective on behavioral problems individuals may wish to change with no focus on weight loss, so could be misinterpreted. Additionally, Ceccarini et al. (2015) indicated that the structure

and internal consistency is poorly understood on the URICA when used for weight management. The DBI has sound psychometric properties and is a reliable measure (Ceccarini et al., 2015), however, it takes external factors like others' opinions into consideration, which was not part of the operational definition of RTC for this study. Another validated RTC tool is the S-weight and P-weight questionnaire, which considers the stage of change and the processes of change for weight loss (Andres, Saldana, & Gomez-Benito, 2011). This is a recognized tool for weight loss; however, several questions were outside the parameters and scope of the definition of RTC that emerged from the existing literature. A concept analysis of RTC resulted in an operational definition that includes an individual's commitment and intention for engagement in the cognitions and tasks required for sustainable weight loss (Wagner & Samra, 2021), and did not include one's thoughts of how others might perceive him/her, such as in the S-weight and P-weight inventory. The tool for the present study, rather, includes questions about the individual making behavior changes that result in a specific outcome. This outcome expectancy, attached to specific weight loss behaviors, is a surrogate measure of self-efficacy (Norcross, Krebs, & Prochaska, 2011), an integral part of the TTM, and aligns with the motivating cognitions from the operational definition. This tool is different from the others because of these questions specific to RTC in specific behaviors for weight loss, such as the planning and preparation for successful completion of the associated tasks necessary for weight loss. While validity and predictive ability of the aforementioned tools have been established, majority of the other existing tools are adapted from other tools used in addiction studies, making it difficult to know if they were founded in the scientific process (Andres, Saldana, & Gomez-Benito, 2011). Additionally, other tools are tailored to very specific targeted populations, making it difficult to apply them beyond the scope of those studies (Kheawwan et al., 2016). Further, research in

weight loss, which is a commonly sought-after behavior modification, often relies on separate RTC tools to measure nutrition and exercise readiness (Ceccarini et al., 2015). Separate tools for the different behaviors, such as dietary changes and exercise, could be problematic to determine stage of change due to the complex relationship between nutrition and exercise for weight loss (Andres, Saldana, & Gomez-Benito, 2011). The RTC tool used in this study asks questions about motivation and commitment to a lifestyle change including nutrition, exercise, and commitment to tracking food and exercise in one tool. Due to the multifaceted nature of weight loss, a single tool may offer a better evaluation of one's readiness to make the behavior changes necessary to achieve desired weight goals.

While some of the existing RTC tools are validated and widely used, others have shortcomings that limit their use. Some of these shortcomings include that the tools were not developed following a scientific process, had no definition that guided development, there was no information on the tool's origin, and the tools cannot be applied to other populations due to their specificity (Ceccarini et al., 2015; Kheawwan et al., 2016). Regardless of the instrument used, validating the stage of change from the TTM is imperative to help understand where individuals are in the process of change and what tasks are most important to help them to continue to make the desired change (Carlo DiClemente, personal communication, June 2021). Therefore, the purpose of this study was to establish content validity, reliability, and psychometric properties of an existing RTC tool that measures readiness for the necessary behavioral modifications of nutrition and exercise for weight loss and disease prevention in a rural population. This research will help further the body of literature on RTC because it follows the rigorous process for tool validation based on a clear, operationalized definition that has the potential to be universally applied to future chronic disease prevention studies that rely on weight

loss as the impetus for change in clinical outcomes. While researchers cannot fully understand a participant's needs through one tool, stage matched intervention is an effective way to help individuals get the means and care they need to continue to be successful with their behavior change (Carlo DiClemente, personal communication, June 2021; Kheawwan et al., 2016).

Methods

Theoretical Framework

The Schilling model for content validity was utilized to establish content validity of the of the RTC tool in this study. Prior to work on self-report measures by Schilling et al., (2007), little validity and reliability work had been completed on these types of tools. The validity, reliability, and psychometric analyses that Schilling and her team performed are still commonly used today and is why this framework was chosen. Content validity was established using content experts and experiential experts in the Schilling et al. (2007) work, so the same process was used for this study. Bernstein's Theory of Psychometrics, which is commonly used to measure internal consistency of self-report tools, was used for psychometric analyses of the tool (Latimer et al., 2011).

Tool Development

This was a survey validation study. Data collection took place between October 2020 and July 2021. The RTC tool was of unknown origin but has been in use by the Montana Diabetes Prevention Program (DPP) for seven years. The sample for the validation study was a subsample of participants in the Montana DPP. To establish content validity of the exiting items, the items were first evaluated against the operational definition of RTC that the authors developed in their previous work using the Rodger's model of concept analyses (Wagner & Samra, 2021). For the

purposes of this research, the operational definition of RTC is the demonstration of one's commitment and intention to engage in motivating cognitions and tasks necessary for sustainable behavior change leading to an expected or desired outcome.

Item Generation and Description of the Original Tool

The original tool had seven items representing the different stages of the TTM model. Participants using the tool were asked to rate their motivating cognitions or tasks indicative of behavior change on a Likert scale from 0 – 4, with 0 indicating "not at all" and 4 indicating "extremely" to the item measures of questions around the domains of motivation, confidence, and expectations. Item scores were added to a total score, and total scores were categorized into stage of change based on the TTM for level of RTC. Scores from the tool categorized people into the precontemplation, contemplation, and the action stages, respectively. A score of 0 – 8 places a person in precontemplation, 9 – 19 means he/she is in contemplation, and 20 – 32 means he/she is in preparation.

Content Validity: Content validity was determined by two panels of experts, a panelist of content experts and a panelist of experiential experts who provided feedback on the original RTC tool.

Content Experts*:* The content experts voluntarily participated in this study. A convenience sample of four content experts that work in instrument development, the psychology of behavior change, and/or diabetes research was selected from professors at a local college in Helena, MT. All of the content experts were PhD trained in their respective fields of psychology and public health. One of the content experts worked with the National DPP for his dissertation, so was knowledgeable in this area of research.

Experiential experts: The experiential experts consisted of five individuals who were recruited from a previous DPP cohort. They had just completed the program, so were knowledgeable about what it entailed. All of the experiential experts who volunteered to help with this validation study were from the same rural area of Montana. They consisted of all females, two in the age category of 18 – 59, and three in the 60+ category.

Content and experiential experts received instructions via email about how to rate the RTC instrument on a clarity and relevance scale, which was sent along with the RTC tool. The framework for evaluating content validity of the instrument was derived from Schilling et al. (2007), which suggests that panelists should rate content validity of each question based on a four-point scale. The scores corresponded to the following from the Schilling et al. (2007) model: 1- not relevant; 2 – question must be revised to assess relevance; 3 – relevant but in need of minor revision; 4 – relevant (Schilling et al., 2007). They rated each item on the tool on a Likert scale and provided feedback on language, items, and any other ideas they had to improve the tool.

Psychometric Analysis. Once content validity was established, a psychometric analysis of the original tool was performed.

Sample for Psychometric Analysis. An initial psychometric analysis was performed on a sample of existing data from 195 DPP participants from previous cohorts that used the original RTC tool prior to validation. The same psychometric procedures were used after the original tool was revised to analyze psychometrics of existing data from a cohort of 38 participants that began the MT DPP program in January 2021. All data represent a convenience sample of existing data from individuals who met criteria for enrolling in the Montana DPP program.

Inclusion criteria for the program is set at a diagnosis of prediabetes and referral from a primary care provider (PCP). Participants can also self-refer based on a series of risk factors outlined by Montana Department of Health and Human Services. To self-refer, participants must be overweight and have at least one of the following risk factors: prediabetes, high blood pressure, high LDL cholesterol, low HDL cholesterol, high triglycerides, or had previous gestational diabetes (Montana Diabetes Prevention Program, n.d.).

Dietitians from the MT DPP administered the RTC instrument to participants at the beginning of the DPP program and at six months. By volunteering to participate in the program, participants provided an implied consent to complete the survey. This study and related methodology were approved by the University of South Dakota Institutional Review Board.

Psychometric Analysis Procedures. A Keiser-Meyer-Olkin test for sampling adequacy (KMO) was performed to determine if adequate sampling existed for tool validation. A Principle Component Analysis (PCA) was performed, and the eigenvalue of the reduced correlation matrix was measured to determine how many components existed. Finally, to measure internal consistency of the individual items, Cronbach's alpha measurements were run on the RTC instrument. These values were used to determine the reliability of the RTC instrument, as well as establish the relatedness of the individual items to one another. The same procedures were followed to analyze the original RTC tool and the revised one after content validity results necessitated changes.

Results

Content Validity Expert Panel

The content validity surveys that were distributed to the content experts revealed that all seven instrument questions received scores of 3 or 4 for clarity and relevance, which correspond to "needs minor revision" for a 3 and "clear" or "relevant" for a 4, respectively. However, comments from multiple expert experts indicated that question seven was leading and might influence participants to answer a certain way due to language about being satisfied with a certain percentage of weight loss. They suggested that question seven should be split into two separate questions. The coefficient of variation for the tool was 9.7%.

Content Validity Experiential Panel

The surveys received from the experiential panel revealed similar results to the expert panel. While the panelists scored the items as 3s and 4s for clarity and relevance, several people wrote in the comments that question seven should be split into two questions and rewritten to reflect "excess weight" instead of capping it at the 7%. Additionally, two panelists also suggested switching the language of a question about fat loss to weight loss.

Psychometric Results of Original Seven Question Tool

The KMO revealed an adequate sample size within the data set with a measurement of sampling adequacy (MSA) value of 0.83 for the original survey, which is above the benchmark for adequate sample size of 0.8. When survey questions were considered individually, every question except number seven had an MSA above 0.8, while question seven had an MSA of 0.7.

The eigenvalue from the reduced correlation matrix on the PCA indicated that there is one component on the tool. The scree plot from the original tool can be viewed in **Figure 1.** With question seven excluded from the original tool, the alpha for the entire tool was 0.8.

Based on the results from Cronbach's alpha on the original RTC tool (alpha = 0.69) and the feedback from the content and experiential experts, question seven was rewritten into two separate questions to reflect outcome expectancies of improved health and weight loss, respectively. The outcome expectancy question focused on improved health and quality of life, and the second outcome expectancy question focused on losing excess weight instead of the specific 7% loss as previously stated on the original survey. Additionally, language was changed on question three to reflect the term weight loss instead of fat loss. This resulted in the RTC tool having eight total questions with a possible score out of 32 instead of 28 on the original scale.

Psychometric Results from the Newly Edited Tool

The Cronbach's alphas on the new tool ranged from 0.54 – 0.68 with a mean of 0.66. The Principle Component Analysis indicated the modified tool had two components. However, after review of the respondent data with all participants answering "4" to question eight, further analysis was performed. Information from a factor analysis indicated that question eight had an eigenvalue of 0, so did not contribute to the variance in the tool. This eigenvalue coupled with the information that all respondents circled "4" for question eight resulted in us suggesting that future studies should exclude this question from the tool. Once this question was removed from analysis, a new scree plot clearly indicated one component, which can be viewed in **Figure 2.**

Discussion

To our knowledge, no tool exists that measures the relationship between RTC and health outcomes in a rural population living with prediabetes who are enrolled in a DPP. Such a tool is necessary to evaluate the effectiveness of interventions aimed at decreasing the progression of prediabetes to type II diabetes in a rural population. Although the original RTC tool has been used to evaluate the effectiveness of interventions in this population of interest for some time, the validity and psychometric properties of the tool had not been established prior to its use.

A concept analysis of RTC was performed and the items on the tool were evaluated against the operationalized definition of the concept by an expert panel and an experiential panel to ensure content validity. Based on this evaluation, the tool did not adequately measure against the operational definition that we identified through the concept analysis. Items in the tool were limited to measurement of motivation, confidence and expectation. Engagement was poorly represented by the items of this tool. The tool was limited to measuring RTC relevant to the initial the three stages of change from the TTM: pre-contemplation, contemplation and preparation . The tool used in this study only focused on these three stages as this was the focus of the Montana DPP, so we did not modify the tool to include more stages so our results were consistent with research across the state.

The results from the validation of the tool necessitated a modification in the tool that resulted in a change from a seven to eight question Likert scale survey. Cronbach's alpha reliability coefficient was 0.66 on this new tool. Additionally, the coefficient of variation for the tool was 9.7%, where under 10% is considered good and indicates that there is an acceptable amount of dispersion around the mean (Searls, 1964). Based on the content validity work and measurement of Cronbach's alpha, the edited RTC tool provides adequate validity and reliability

for a new measure of RTC in rural populations living with prediabetes who are in one of the initial three stages and for screening participants prior to entry into an intervention program such as the DPP This would be an acceptable or reasonable brief measure to perform initial screening of readiness of individuals with prediabetes to enter an intervention program. The tool is, however, not appropriate for studying RTC in individuals who are in action or maintenance stages. It is important to note that content validity is the first step in establishing validity and future work is needed to establish construct and predictive validity.

We followed the parameters set forth by Nunnally (1967) for psychometric analyses to determine reliability of the RTC tool. Cronbach's alpha for reliability is an important measure for a summated scale such as this one to help researchers know that there is adequate internal consistency among the individual items (Vaske, Beaman, & Sponarski, 2017). An alpha of 0.65 – 0.8 is generally considered acceptable (Vaske, Beaman, & Sponarski, 2017), so an alpha of 0.66 with a range of 0.56 – 0.69 is a reasonable alpha for a new tool with a small sample size (n = 38). Ideally, a larger sample size would be used to establish the alpha, however, that was not possible given the convenience sample used in this study. Similarly, Nunnally and Bernstein (1994) state that the recommended Cronbach's alpha for a new instrument is 0.7, so this newly validated tool was close to this value. The modified tool initially had two components after a PCA was performed, but was reduced to one component after a review of the data indicated that question eight did not fit well with the rest of the questions and should be rewritten to better capture outcome expectancy attached to readiness for behavior change. It currently reads as "Would you be satisfied with losing excess weight," but does not attach a readiness component to capture how ready individuals are to make the changes necessary to reap said benefits.

The RTC tool uses a summative score Likert method to place individuals into either the precontemplation, contemplation, or preparation stages based on the TTM. It does not include the action, maintenance, or relapse stages as the intent was to determine if individuals were ready to begin the action stage of the DPP. If they were in the action or maintenance stages, they would likely not need the program in the first place. Exclusion of the action, maintenance, and relapse stages on the tool is similar to previous studies where the goal was to measure the RTC of individuals at the beginning of a program, not when they are already making progress towards their goals (Kweahhan et al., 2016; Rollnick et al., 1992).

When compared to other validated tools, such as the URICA, DBI, and S-Weight and P-weight, this tool offers something different. For purposes of this cohort, understanding the placement of participants into the first three stages of the TTM was important to determine readiness to begin a chronic disease prevention program. The URICA does not include measurement of the preparation stage (Kweahhan et al., 2016), which comes right before the action stage, so was deemed necessary here. Measuring preparation in a population already enrolled in the DPP could indicate that they're already in the preparation stage, so could be a reason why other scales like the URICA do not measure this, however, results indicated that not everyone was in preparation. Some psychotherapy research considers the influence of others on decision making, which is measured in the DBI and S-weight and P-weight (Ceccarini et al., 2015), but was outside the scope of this study based on the operational definition that emerged from Wagner and Samra (2021). However, this RTC tool, like the S-weight and P-weight, was geared specifically towards weight loss with some similarity in questions.

The current results will improve understanding of the stages of change for weight loss for enrollees in a weight loss program for chronic disease prevention, prior to the action stage, so

researchers can better target stage-matched interventions prior to action stage. Currently, participants in the DPP get the same intervention regardless of what level of readiness they are in at the beginning of the program. Each stage of the TTM has associated knowledge and skills that one must master to move onto the next stage (DiClemente et al., 2004), so knowing participants' RTC could help DPP program administrators target appropriate assistance based on stage. As Kheawwan et al. (2016) indicate, most programs deliver action stage content, so may entirely miss helping those in lower stages of readiness who need help moving towards action. This aligns with Dr. DiClemente's statement that there is no one-size-fits-all program (personal communication, June 2021), so measuring RTC is a step in the right direction to help all participants in a program, not only those who are ready to take action.

Limitations

There were several limitations to this study. The greatest limitation to this research was that the original RTC tool was of unknown origin. While it was clearly developed based on the TTM, there is no way to know if the original tool was valid and the applications of its use. There are clear methodologies used in tool development and we are not certain those were followed when the original tool was developed. However, establishing its content validity against a well-defined concept minimizes this problem. Additionally, this study is limited by a small pilot sample of 38 people in one rural geographic area in Montana, which is not representative of all rural populations. Helena and Townsend, MT, where the pilot study was performed, have higher household incomes and different economic opportunities than other more rural areas of Montana, and socioeconomic status is a major consideration as a social determinant of health in rural areas (Thomas et al., 2014). Thirty-eight is also a small sample size but was the size of the cohort enrolled in the DPP starting in January 2021. It is generally accepted that there should be 10 respondents per item on a scale for reliability purposes (Nunnally, 1967), however, given the constraints of the size of the development sample (n = 38), this was not feasible, so is also a limitation of this study. A further limitation of this study is that concurrent validity with other validated RTC instruments was not performed, which limits the relatability of this instrument to literature that has been done in this area utilizing validated instruments. Finally, reliability was a limitation of this study. While we had a Cronbach's alpha close to the suggested range, it was still a lower score, and we also did not measure test-retest reliability.

A further limitation of this study is that we used an RTC tool that measured the first three stages of change from the TTM: pre-contemplation, contemplation, and preparation. This tool

did not include measurement of the action or maintenance stages, so did not capture any participants who were in these latter stages of change. However, the tool serves as a good entry evaluation to help researchers gauge readiness for beginning a new program. For future studies, the tool should be expanded or used concurrently with another tool that measures action and maintenance to measure baseline stage of change of all participants more accurately so researchers can better tailor interventions and support.

Conclusion

In conclusion, results from this preliminary study document content validity of the RTC tool, indicating it is a reliable way to measure RTC in rural populations living with pre-diabetes and who are in one of the pre-action stages of the TTM and referred to the PDP. Future studies should expand the tool to measure all the TTM stages and ensure alignment with the operational definition of RTC identified through this work,. Validity of the items specific to this tool was confirmed by expert and experiential experts. Cronbach's alpha of the modified tool was in an acceptable range, especially for a new tool with a small sample size. This study helps further the body of knowledge by offering a measure that has its theoretical underpinning from the TTM and clearly places individuals into one of the initial three stages of the TTM. Such measure has an important utility to screen for RTC in pre-intervention stages and can be used as an indicator of RTC level pre-admission of rural participants with pre-diabetes into intervention programs such as the DPP (DiClemente, personal communication, June 2021). Future research in this area should use a larger sample size to provide a more accurate measure for reliability statistics. A concurrent validity study against other validated weight loss tools like the S-weight and P-weight would also provide good information moving forward. The S-weight and P-weight Inventory measures all stages of the TTM while simultaneously measuring processes of change (Ceccarini

et al., 2015), so measuring this concurrently with the tool in this study could help us understand how it holds up to a more robust tool that measures all stages. It is possible that by measuring motivation, commitment, and outcome expectancy, but not action, as in the current RTC tool, we missed those who were already in the action or maintenance phases, which could have resulted in lower internal consistency. Future research should consider expanding the tool to measure the action and maintenance stages so that researchers can capture all possible stages of change prior to participants beginning an intervention program.. Further, future research should also work to establish construct and predictive validity. Ultimately, many chronic disease prevention programs rely on weight loss for clinical benefits, and this tool's questions specifically target readiness for weight loss. Due to addressing this need, it has the potential to be broadly applied to other programs to help the fight against preventable chronic disease in rural areas of the United States.

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Figures

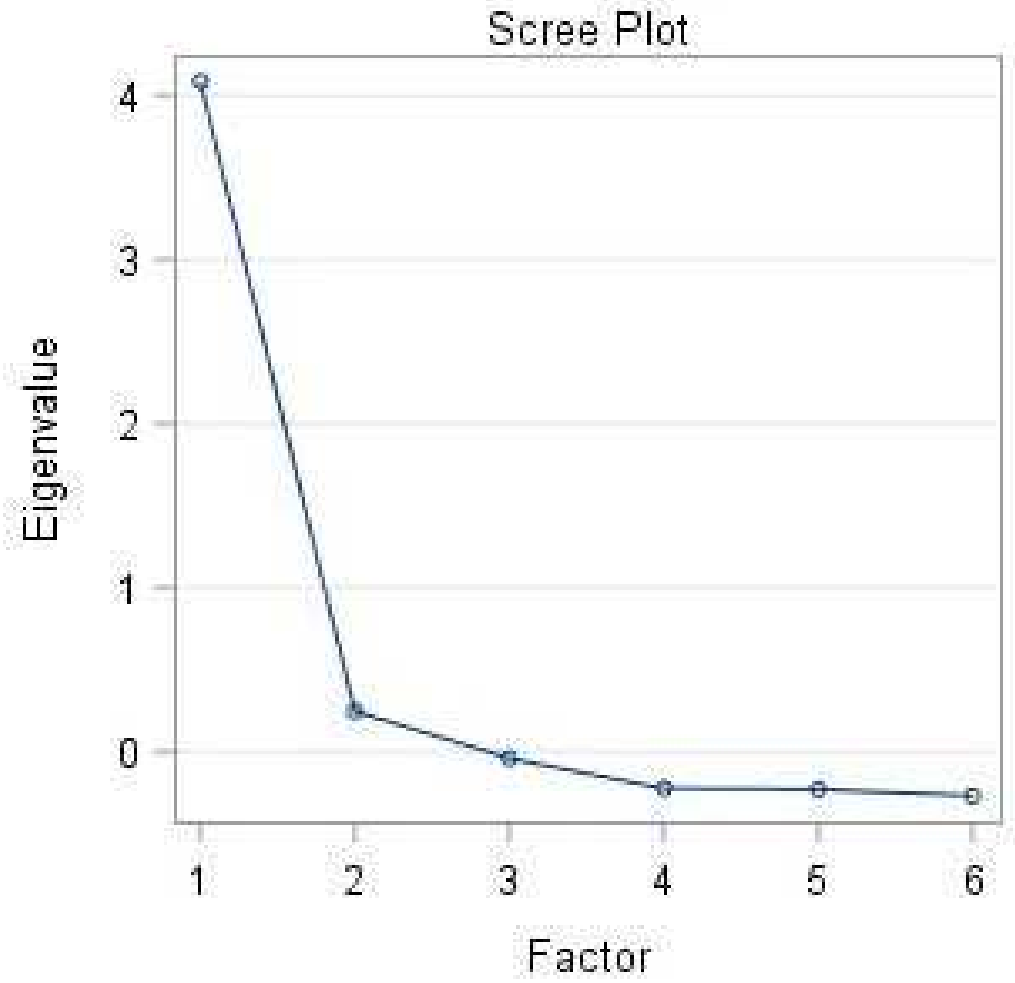

Figure 1 – Scree plot of original RTC tool without question 7 indicating one component.

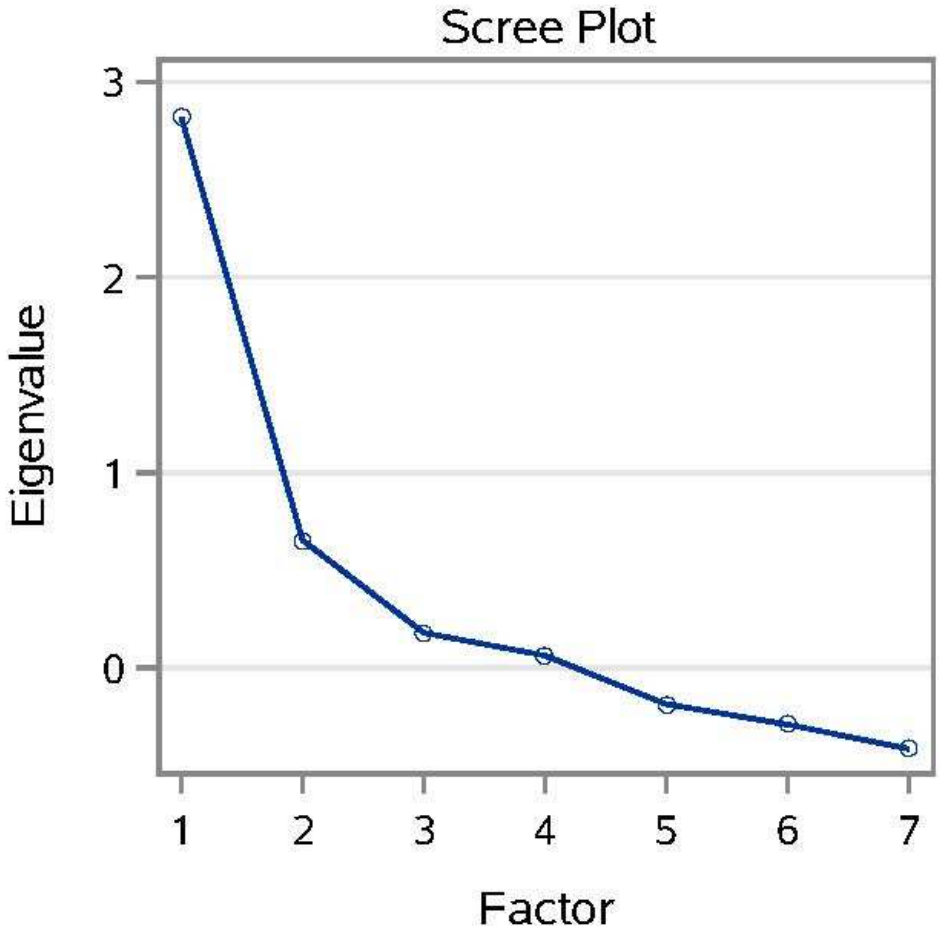

Figure 2 – Scree plot of newly validated tool without question 8 indicating one component.

Chapter 4: Readiness to Change in Rural Adults with Prediabetes

Abstract

The burden of chronic disease in America affects not only lifespan, but also quality of life and healthcare costs for individuals and the nation, and type II diabetes is a chronic disease that is growing rapidly. Lifestyle behaviors such as nutrition and physical activity form the foundation of type II diabetes risk, yet changes in these same behaviors also offer the key to disease prevention. The National Diabetes Prevention Program is the evidence-based practice model for preventing the progression from prediabetes to type II diabetes through nutrition and physical activity that results in modest weight loss, yet cases continue to soar at alarming rates. Additionally, rural dwellers face unique challenges that could reduce their likelihood of staving off the disease. The purpose of this study was to examine the relationship between readiness to change and attrition rates, and readiness to change and the clinical outcomes of blood glucose, hemoglobin A1C, and weight among a sample of 38 rural dwellers enrolled in the Montana Diabetes Prevention Program. Readiness to change scores and clinical measures were measured at baseline of the program and again at six-months. Results indicated that the covariates of income and geography significantly modified the relationship between readiness to change and attrition, but not significantly between readiness to change and weight, hemoglobin A1C, and blood glucose. However, a moderately strong effect size of 0.65 could indicate clinical significance.

Key words: readiness to change; diabetes prevention; rural health

Article 3: Readiness to Change in Rural Adults with Prediabetes

Type II diabetes is a growing epidemic that significantly contributes to the burden of chronic disease in the United States (CDC, 2019). Effective diabetes treatments such as medications, diet, and exercise exist, but a diagnosis of diabetes puts a person at high risk for a host of other comorbidities (CDC, 2019). While roughly 30 million people in the United States have diabetes, a staggering 84 million have prediabetes, which is over 33% of the population (CDC, 2019). Individuals with prediabetes are at great risk of developing type II diabetes in the next five years without taking action to prevent this progression, and many of these people are not even aware that they have prediabetes (CDC, 2019). Current evidence-based practice places precedent on diet and exercise as the key preventative factors to stop the progression of prediabetes to type II diabetes (American Diabetes Association, 2013). However, with an estimated 1.5 million new diagnoses of diabetes in 2015 (CDC, 2019), it is evident that a barrier still exists to preventing type II diabetes and there is an urgent need to find effective prevention tactics.

The National Diabetes Prevention Program (DPP) is an evidence-based program that emphasizes improved nutrition and exercise to promote weight loss, with a target of 7% weight loss during the program to help halt the progression from prediabetes to T2DM. This benchmark level of weight loss has been shown to improve risk stratification for those individuals who are diagnosed with prediabetes who participate in the program (CDC, 2018). Maintaining the behaviors that result in sustained weight loss, and therefore improves risk status, proves difficult for people in weight loss programs (Ceccarini et al., 2015). Many people who go on to lose weight regain it over time (Sumithran & Proietto, 2013), indicating that the initiation of weight

loss is not the primary hurdle, but maintenance of the behaviors that resulted in weight loss is problematic (Ceccarini et al., 2015). This underscores the importance of helping people create sustainable behavior change for long-term weight loss.

Theoretical Framework

Ceccarini et al. (2015) indicated that RTC is of great importance not only for motivation to begin behavior change for weight loss, but also to persist with this change. Readiness to change allows for measurement of the stage of change from the transtheoretical model of change (TTM) (DiClemente et al., 2004). The developers of the TTM asserted that behavior change participants go through a series of stages on the path to sustained behavior change, and that the TTM would provide researchers a model to understand the processes that occur to foster this change (DiClemente et al., 2004; Prochaska & DiClemente, 2015). The stages in the TTM include precontemplation, contemplation, preparation, action, maintenance, and relapse. These stages have a temporal element because individuals move through them at different times and because each stage has a suggested time frame associated with it (Sarkin et al., 2001). Most people do not move through the stages in a linear fashion, but rather move back and forth, then move through cyclically (Sarkin et al, 2001). The TTM is the clear theoretical underpinning of the measurement of RTC, however, DiClemente and colleagues (2004) made a clear distinction between readiness and the TTM itself by stating that readiness is a more generic term implying intention or willingness to initiate change. Dr. DiClemente (personal communication, June 2021) expressed that RTC is a great tool to help researchers better understand how to help people make sustainable change, but that people cannot be placed in boxes. He said that measurement and validation of the stage of change is an important step researchers can take to help connect

individuals with the programmatic education and support they need to be successful (personal communication, June 2021).

Background

Measuring RTC in chronic disease prevention and treatment programs is not new. A multitude of studies use RTC levels to try to predict patterns of health behavior change with researchers providing evidence that RTC is reliable and valid (Prochaska et al., 2013). A study by Helitzer and colleagues (2007) indicates that RTC is a strong predictor of attendance for rural American Indian women in a program similar to the DPP, with a significant relationship between stage of change from the TTM and attendance rate. Research by Swan and colleagues (2006) focused on rural women with previous gestational diabetes, a risk factor for later development of type II diabetes. They found that even with knowledge of diabetes prevention efforts and their higher risk for developing the disease, these women did not make behavior changes necessary to effect change (Swan et al., 2006). Vallis et al. (2003) used the stages of change from the TTM to predict adherence to a prescribed diet intervention and associated clinical outcomes for diabetes management. While some research exists on RTC and diabetes prevention, it has not been well studied in rural adults with prediabetes. Research suggests that rural dwellers face unique challenges based on culture, lack of economic opportunity, and geographic location, however, the studies that do exist are on specific populations so are not representative of most individuals living in rural areas (Thomas et al., 2014). Roughly 70% of Montanans live in rural areas and Montana has a 13.4% poverty rate (Rural Health Information Hub, 2018), so meets two of the criteria set forth by Thomas and colleagues (2014) for individuals facing the rural triad of health disparities. Culture, the third criterion in the rural triad, is of interest for Montanans, but measurement of this variable was beyond the scope of this study.

As discussed above, there is a clear need for greater understanding of how to help people with prediabetes stop the progression to type II diabetes. However, there is a gap in knowledge regarding RTC in rural populations following a nutrition and exercise program to achieve this end. Therefore, the purpose of this research was to study the relationship between RTC and clinical outcomes among rural adults with pre-diabetes following a nutrition and exercise program as prescribed by the DPP in Montana. New knowledge in this area could help reduce the burden of chronic disease in the United States, especially in rural areas. This research was conducted in collaboration with the Montana DPP as a pilot study of a newly validated RTC tool in a rural, medically underserved part of Montana. There are modifiable and preventative characteristics of many chronic diseases, including for type II diabetes. However, understanding how behavior change works and how to facilitate progress towards change is paramount to understanding how to foster sustainable, long-term change to help individuals reap the anticipated health outcomes. Furthermore, preventing the progression of prediabetes to full-blown type II diabetes is more cost effective than treating the disease and the associated comorbidities and complications (Herman, 2015).

Specific Aims and Hypotheses

Specific Aim 1. The first specific aim of this study was to determine the relationship between RTC and attrition rates in a nutrition and physical activity program delivered by the Montana DPP to rural adults with prediabetes. There are three hypotheses:

> *Hypothesis #1:* It was hypothesized that higher RTC scores would be associated with lower attrition rates.

Hypothesis#2: It was hypothesized that dropout rate would be higher for individuals in the precontemplation stage than those in the contemplation and preparation stages of the TTM.

Hypothesis #3: It was hypothesized that lower income and rural geography would modify the relationship between RTC and attrition rates unfavorably.

Specific Aim 2. The second specific aim was to determine the mediating effect of selected psychosocial factors on the relationship between RTC and clinical outcomes six months after initiation of a healthy eating and physical activity intervention. There are two hypotheses:

Hypothesis #1: It was hypothesized that of those who stayed in the program for the full six-month timeframe, those with greater baseline RTC scores would also have greater weight loss, and lower blood glucose and HbA1C at six-months.

Hypothesis #2: It was hypothesized that lower income and rural geography would affect the relationship between RTC and the clinical outcomes of weight loss, blood glucose, and HbA1C unfavorably.

Methods

Study Design

This study was a longitudinal, correlational design that used existing data for analysis. Readiness to change tools were administered by registered dietitians and exercise coaches at baseline and six-months in a rural sample of participants in the Montana DPP.

Procedures

Once enrolled, participants completed demographic paperwork, completed the validated RTC tool, were weighed and measured, and had bloodwork drawn as part of the MT DPP. The DPP is a year-long program that meets in-person for weekly sessions for the first six months, then monthly for the duration of the program. Diabetes prevention content was delivered by registered dietitians and exercise coaches for an hour at each session. This evidence-based program is based on research that indicates that weight loss of 7% for high-risk individuals can reduce the risk of development of type II diabetes by 58%, and is achieved by a lower calorie diet and 150 minutes of physical activity per week (CDC, 2018). Participants were weighed and turned in a food log each session. The RTC tool was given again at the six-month follow-up that coincided with a blood draw to measure clinical outcomes at this time point.

Participants and Recruitment

Existing data from the Montana DPP were used for this study. Participants were members of the DPP program that took place in Helena and Townsend, MT that began in January of 2021, so were a convenience, non-randomized sample. Participants were either referred to the program from a medical provider or self-referred based on the following inclusion criteria. To be included in this study, participants had a BMI of 25 or greater and had at least one additional risk factor that placed them at high risk for developing type II diabetes.

These additional risk factors included:

- Fasting blood glucose of 100 – 125 mg/dL
- HbA1C of 5.7 – 6.4%
- Blood pressure of 130/80 mmHg or higher
- Triglycerides greater than 150 mg/dL

- LDL cholesterol of 130 mg/dL or on treatment for high cholesterol
- HDL cholesterol less than 40 mg/dL for men, or less than 50 mg/dL for women
- History of gestational diabetes,
- Score greater than a 5 on the Prediabetes Risk Test administered by the DPP.

Outcomes of Interest

Readiness to change

Readiness to change, which was the primary independent variable for the purposes of this study, was measured using an RTC tool that was reliable and valid as determined from a validation study by Wagner and Samra (2021). Readiness to change was analyzed as a continuous variable to analyze strength of score on the tool, and categorically to consider the stage of change a participant was in based on their score. This tool contains eight questions and is a summative survey that gives RTC scores that correspond to the first three stages of change from the TTM, precontemplation, contemplation, and preparation, respectively. A score of 0 – 8 indicated precontemplation, 9 – 19 indicated contemplation, and 20 – 32 indicated preparation. Readiness to change scores were measured for each participant at baseline and six-months into the program. Measuring stage of change via RTC is an important step for researchers to take in predicting programmatic outcomes (Dr. DiClemente, personal communication, June 2021). Readiness to change scores were analyzed against attrition rates and outcomes to determine what relationships were present. Covariates were controlled for in a logistic regression model to determine if they influenced these relationships. The RTC tool was administered on paper to participants by registered dietitians during their intake appointment at the beginning of the

program. They were administered via mail survey at six-months due to the program being delivered digitally due to the COVID-19 pandemic.

Attrition rates

Attrition rates were measured from baseline to six-months of the program. Attrition was a dependent variable in this study as we were looking for how RTC levels at baseline affected attrition rates. The program met weekly, so attrition was tracked to the week a participant dropped out. Two attempts were made by program staff to contact participants before confirming that they were lost to follow up. Attrition is recognized as a large barrier to success in diabetes prevention programs (Helitzer et al., 2007). Helitzer and colleagues (2007) indicated that stage of change at baseline is a strong predictor of attendance in American Indian women in a program similar to the DPP. Their study was shorter, with five sessions, while the current study examined attrition over a six-month period.

Weight loss

Weight loss was a dependent variable in this study and was measured weekly from baseline to six months. Research suggests that modest weight loss of 5-10% of body weight can have significant health benefits, and the DPP research suggests that losing 7% of one's weight can prevent the progression of prediabetes to diabetes by as much as 58% (CDC, 2018). The recommendation of 7% weight loss comes from the large clinical research study that showed substantial decrease in risk of type II diabetes for individuals who lost between 5-7% of their body weight following a reduced calorie diet and achieving 150 minutes of moderate intensity exercise per week (CDC, 2018). Proper nutrition and physical activity help keep blood glucose in a normal range, as well as help prevent obesity (American Diabetes Association, 2013). The

National DPP was born from this research, so the MT DPP follows weight loss guidelines set by this landmark study. Weight was initially measured by registered dietitians using a digital hospital grade scale and the same scale was used for the six-month outcome data. Weight was measured at the same time of day and by the same two registered dietitians.

Blood Glucose

Blood glucose, another dependent variable, is of primary interest in this study as it is part of the diagnostic criteria for prediabetes and diabetes. A fasting blood glucose of 100 – 125 mg/dL on two separate occasions is one of the diagnostic criteria for prediabetes, while a fasting blood glucose over 125 mg/dL on two separate occasions is used for diagnosing diabetes (American Diabetes Association, 2013). This was used to determine effectiveness of the program in preventing progression of prediabetes to type II diabetes and was measured at baseline and six-months of the program. Blood glucose was measured at both baseline and six-months in a fasted state via venipuncture by a certified phlebotomist at St. Peter's Health Laboratory.

Hemoglobin A1C

Hemoglobin A1C is another dependent variable measured in this study. A measurement of one's HbA1C indicates the amount of blood glucose attached to a person's hemoglobin and is a good measure of blood glucose over a period of about three months (Koenisberg & Corliss, 2017). It is a reliable measurement for diagnosing prediabetes and diabetes, with an A1C of 5.7% - 6.4% or above 6.4%, respectively (Koenisberg & Corliss, 2017). This was measured at baseline and six-months into the program to determine if RTC was related to diabetes prevention outcome measures. Hemoglobin A1C was measured at both baseline and six-months in a fasted

state via venipuncture by a certified phlebotomist at St. Peter's Health Laboratory. This is a standard blood measure for determining the amount of glucose attached to hemoglobin and the ranges listed above are criteria for diagnosis of prediabetes or diabetes (American Diabetes Association, 2013).

Demographics

The sample of participants in this study was from a rural geographic area in Montana. The study began with 38 participants, but after loss to follow-up, 28 were analyzed. Demographic variables measured from participants at baseline included age, gender, race, income, education level, and geographic location. These demographic data were collected via self-report questionnaires that were administered by two registered dietitians at the intake for the program. The cut-off values for age and income were determined previously by the DPP.

Covariates

Possible covariates of interest examined in this study were income and geographic location. Evidence suggests that people who live in rural areas face health disparities related to their ruralness that their urban counterparts do not face (Thomas et al., 2014). Specifically, they suffer poorer health outcomes related to their geographic location, culture, and lack of economic opportunity (Thomas et al., 2014), of which geographic location and income were examined in this study. Education is related to income, and health outcomes tend to improve with higher educational attainment and income potential (Pollock et al., 2013).

Ruralness was an important factor in this study and had the potential to impact results. The U.S. Census Bureau does not have a clear definition of a rural area, however, state that an urban area is defined as having 50,000 or more people (Health Resources and Service Administration, 2021). Helena, MT is a community of roughly 30,000 people, and Townsend,

MT, the other community that participated in this study that receives medical service from Helena has a population of just over 2,000. It is common for the smaller communities in Montana to receive healthcare and get essential services from regional centers such as Helena in this case (Rural Health Information Hub, 2018). In general, the entire population for this study is considered rural. Helena offers a regional hospital which serves Townsend and other small communities, yet still does not meet criteria as urban since there are not 50,000 people (Rural Health Information Hub, 2018). For this study, those who lived in Townsend or out of city limits were denoted as rural in the data and tables**,** while those in Helena city limits were considered urban for purposes of discussion. It was important to understand how these demographic variables may or may not have influenced the primary questions of interest of RTC score on clinical outcomes. After the main analyses were performed to answer the question about the relationship between RTC and outcomes, further analyses were performed to determine if the relationship was modified based on these demographic variables.

Sample Size

This was a convenience sample of existing data from 38 participants enrolled in the DPP in one rural geographic area of Montana. This pilot study used a newly validated RTC tool from a previous study by Wagner and Samra (2021b). For a new tool, Nunnally (1967) suggests that there should be 10 respondents per item, and there were eight items on the survey, but given that this was a pilot study, this was not feasible. A sample size of 169 people was calculated post-hoc using the minimum detectable odds ratio for RTC and blood glucose (**Table 4)** with power at 80% and a 5% significance level. Therefore, future studies should use a sample of at least 169 people to analyze the relationship between RTC and clinical outcomes using the methods in this study. The effect size, using Hedge's g, was measured at 0.65.

Assessments

Instrumentation

Participants completed the RTC tool at the start of and six months into the MT DPP program. The original version of this tool was of unknown origin and attempts to find its original origin were not successful. We did not have information about the background or construction of the tool, although it did measure stage of change from the TTM. It had been used by the MT DPP for several years prior to this study. Content validity and psychometric analyses were measured on the existing tool using data from previous years of the DPP. These validity and psychometric analyses resulted in a slightly altered tool that had adequate internal consistency and established content validity for use in this study. The researchers had a data use agreement with the MT DPP to utilize necessary, existing data for this dissertation and worked with a statistician from the MT DPP.

Statistical Methods

Descriptive Analyses

A descriptive analysis was performed on participant demographics to understand how they were distributed among this sample. Frequency distributions were run on the demographic variables of age, income, employment status, sex, geographic location, and education as these were measured categorically at baseline. Age was also measured continuously, so there is also a mean and standard deviation for age. Descriptive statistics of mean and median were run on the independent variable of RTC and dependent variables of HbA1C, fasting glucose, and weight. The original plan was to break data into categories based on levels of RTC, however, every participant scored in the preparation stage of RTC, so they could not be broken down further.

Inferential Analyses

To respond to the hypotheses about attrition, an independent t-test was performed to determine relationship between baseline RTC and attrition. A bivariate analysis was conducted between RTC and demographic variables to determine if there were associations with RTC for inclusion in logistic regression. A logistic regression was then performed to determine if there was a relationship between RTC and attrition with income and geography as covariates due to their suggested influence on health outcomes (Thomas et al., 2015). A logistic regression was done to analyze the hypotheses regarding the relationship between RTC and clinical outcomes of weight, blood glucose, and HbA1C. Variables were dichotomized for the logistic regression based on the likelihood of "yes" or "no," so for example, yes that people lost weight, or no they did not. Due to a small sample size we limited the covariates included in the analyses to income and geography to determine if they mediated the relationship between RTC and outcomes. An assumption of logistic regression is a large sample size, which was not available, so utilizing two potential covariates is a limitation of this work.

Results

Descriptive Results

A breakdown of the demographic variables of age, income, geography, employment status, education level, sex, and race indicate a mostly representative sample from the area, and can be viewed by frequency distribution in **Table 1.** Majority of participants were female (84.2%), which is similar to data from the DPP across all sites in Montana with an average of 82% female (Montana Diabetes Prevention Program, 2020).

There were improvements in key diabetes prevention variables from baseline to six-months, namely that HbA1C ($p = 0.002$) and weight ($p = 0.009$) significantly improved, while blood glucose did not change significantly (**Table 2**). Additionally, RTC score dropped from baseline to six-months and was statistically significant ($p = 0.009$) (**Table 2).** Changes within participant scores can be viewed in **Table 3.**

Attrition Rate

Overall, there was an attrition rate of 26% from baseline to six-months among this sample, while there is an average attrition rate of 30% in the DPP across the state when delivered digitally. This indicates that the sample was similar to the attrition from the program across Montana. The demographics of those who stayed the full six months compared to those who were lost to follow-up can be viewed in **Table 4,** but there were no significant differences between groups**.** The first hypothesis was that higher RTC scores would be associated with lower attrition rates. The mean RTC score for those who stayed in the study was 27.4 (±2.4 standard deviation), while the mean score for those who were lost to follow-up was 29.1 (±3.2 standard deviation). An independent t-test indicated that there was not a significant relationship between RTC and attrition at baseline ($p = 0.09$), so the first hypothesis was refuted.

The logistic regression after adjustment for income and geography indicated that there was a significant relationship ($p = 0.04$) between RTC and attrition rates (**Table 5)**. These results signify that the covariates of geography and income confounded the relationship. The effect size calculated by Hedges' g ($g = 0.65$) indicates a moderately strong relationship between these variables, which adds strength to this finding. However, effect size should be interpreted with caution here due to the small sample used in the logistic regression (Greenland, Schwartzbaum & Finkle, 2000). Additionally, when comparing the baseline demographic variables and baseline

continuous RTC scores (**Table 4)**, none of the demographic variables were significantly related, although education did approach significance ($p = 0.06$).

Finally, it was hypothesized that dropout would be higher for individuals in the precontemplation stage as compared to the contemplation or preparation stages of the TTM. Limited variation among the RTC stage made this hypothesis untestable because every participant scored into the highest stage, preparation, from the RTC tool at baseline, so none fell into the precontemplation stage. These results are interpreted with caution due to the small sample size of this study.

RTC and Clinical Outcomes

It was hypothesized that of those who stayed in the program for the full six-month timeframe, those with greater baseline RTC scores would also have greater weight loss, and lower blood glucose and HbA1C at six-months. **Table 6** presents results from the logistic regression analysis between the independent variable of RTC and possible covariates of income and geography on the clinical outcomes of decrease in weight (lbs), blood glucose, and HbA1C. The analysis revealed that RTC, geography, and income were not significantly associated with the clinical outcomes. Readiness to change score and geography approached significance in relation to blood glucose, both with *p*-values of 0.07, but were not significant. The odds ratio between RTC and blood glucose also was the most precise with a point estimate of 1.6 and confidence interval of 0.9 – 2.9, however, the odds ratios and confidence intervals from all other variables indicated wide variability (**Table 7)**. Therefore, we fail to reject the null hypothesis that there was no independent relationship between RTC and the variables of weight loss, decrease in HbA1C, and decrease in blood glucose in this pilot study.

The second hypothesis under the aim of understanding the relationship between RTC and clinical outcomes was how select psychosocial factors affect clinical outcomes. It was hypothesized that low income and rural geographic location would affect the relationship between RTC and the clinical outcomes of weight loss, blood glucose, and HbA1C unfavorably. However, results from the logistic regression (**Table 6)** indicated there neither variable affected the relationship between RTC and outcome measures. Therefore, we fail to reject the null hypothesis that neither income nor geography modified the relationship between RTC and clinical outcomes of blood glucose, HbA1C, and weight.

Discussion

In order to better understand how to serve individuals working to combat the progression of prediabetes to diabetes, we evaluated how RTC affected attrition rates and clinical outcomes of weight, HbA1C, and blood glucose in a sample of rural adults in the MT DPP. Stage-matched intervention is an important goal of measuring stage of change associated with the TTM, and RTC offers a way to measure the stage (Prochaska et al., 2013). To our knowledge, the effects of RTC with the select covariates of income and geography have not been well studied in this prediabetic, rural population due to prior studies focusing on specific populations that were not generalizable. Previous studies in RTC literature have suggested that RTC stage is predictive of achieving successful outcomes and gives researchers insight into how to target education, motivation, and necessary materials to help individuals in behavior change programs realize their goals. However, there were no significant findings in this study that support the finding from these previous studies. Given the sample size and limitations of this study and inability to compare differences between stages, results should be considered carefully.

Attrition Discussion

All participants in this study expressed high motivation, confidence, and outcome expectancy at the start of the study, which is indicative of being in the preparation stage of the TTM. The operational definition of RTC for this study was the demonstration of one's commitment and intention to engage in motivating cognitions and tasks necessary for sustainable behavior change leading to an expected or desired outcome. All participants measured into the preparation stage at baseline, which indicated they were preparing to act, yet there was a 26% attrition rate in the program. Based on the independent t-test, readiness to change stage was not predictive of attrition rate like originally hypothesized. To support that hypothesis, those who dropped out would have needed to have been in lower stages of change, specifically precontemplation, but that was not the case in this study, and there was not a significant difference in RTC scores between those who stayed versus those who were LTF. research should consider if this difference in score is meaningful even though all participants were in the same stage of change. These findings oppose research by Helitzer et al. (2007) who found that stage of change was a strong predictor of attrition in a program similar to the DPP such that the higher the stage, the less likely people were to be lost to follow-up. While the relationship was not significant from the t-test, there was a significant relationship from logistic regression when covariates of income and geography were included in the model, indicating that they did modify the relationship between RTC and attrition. An effect size of 0.65 also adds strength to this relationship, however, should be interpreted cautiously due to the small sample size. This does suggest that these measures that commonly affect people who live in rural areas could impact attrition rates. This is logical as people who have lower income or are in more rural areas tend to have less opportunity and less access to programs and healthcare (Thomas et al., 2014). While

participants could have left for a myriad of reasons, it appears there was a barrier between their perceived high levels of motivation, commitment, and outcome expectancy and following through with the program. There is the possibility that as those individuals entered the action stage which require higher and more intense levels of commitment and motivation, they got disengaged and quit. however, this could not be measured in this study since we did not measure the action stage or the processes associated with the TTM. The preparation stage indicates that an individual has taken appropriate steps to begin behavior change but does not necessarily indicate that the action was sustained. (Prochaska et al., 2014),. The S-weight and P-weight Inventory measures both the processes of change and readiness (Ceccarini et al., 2015), and suggest the importance of measuring both as well as measuring activities associated with the stages. We did not measure activities associated with the stages of the action or maintenance phases. It is logical that despite high preparation as measured by the RTC tool, as people entered the action stage they encountered barriers or lacked the skills necessary to continue taking action. A benefit of measuring RTC stage is using that information to provide stage-tailored resources and information to help participants overcome real and perceived barriers to continue with behavior change (Ceccarini et al., 2015). Perhaps by not measuring action and maintenance we missed measurement of a group of people who needed different support, so were lost-to-follow-up.

An extenuating circumstance that may have had a large impact on attrition is the COVID-19 pandemic. We were unable to determine the reasons why people left the study, but the program was delivered in a digital format to allow for social distancing to prevent the spread of COVID-19. Therefore, the program was delivered via Zoom. A possibility for the attrition rates could be Zoom fatigue, or lack of interest or competency in utilizing videoconferencing.

Bailenson (2021) mentioned that Zoom fatigue results in a lack of nonverbal communication and increases cognitive load to remain focused on the topic. Nonverbal communication helps people stay engaged in a conversation or lesson, so without it, people may have disengaged, which may have reduced their interest resulting in dropping from the program. Additionally, stressors from COVID-19 could have influenced attrition rates and outcomes in this study. We were unable to predict these constraints and how they might affect participants at the start of the study, so its difficult to speculate what attrition would have been like for this sample had the program been delivered in the traditional face-to-face format.

Outcomes Discussion

Neither RTC score alone or RTC with covariates of income and geography were associated with the clinical outcomes of weight loss, blood glucose improvement, or HbA1C improvement. Considering the moderately strong effect size ($g = 0.65$), there could have been clinical significance among these results even though there was not statistical significance. This is particularly relevant for blood glucose and RTC as this relationship approached significance.

As previously stated, every participant scored into preparation, the highest stage of RTC on the tool. Individuals who live in rural areas often face different challenges related to their ruralness (Thomas et al., 2014), and it was hypothesized that income and geography would modify the relationship between RTC and clinical outcomes. People who live in rural areas tend to have fewer economic opportunities, face challenges due to their geographic location, and have differences in culture than can affect their health (Thomas et al., 2014). Given a larger sample size we would have been able to analyze more possible covariates related to ruralness, specifically age, education, and employment status. Additionally, given the COVID-19 pandemic, there could have been other confounders, such as stress or anxiety and depression

surrounding the pandemic that could have altered any relationship between RTC and clinical outcomes.

High total RTC scores at baseline indicate that motivation, confidence, and outcome expectancies were high for all participants. These were considered under the one main component of RTC for the tool by factor analysis in the validation study previously performed (Wagner and Samra, 2021), but were broken down for scoring the items. These cognitions are important to initiate and sustain behavior change and were included in the operational definition of RTC for this study. However, Swan and colleagues (2006) suggested that there can be a gap between RTC and taking action that results in desired outcomes, which could help explain why RTC and outcomes were not related. Perhaps using an RTC tool that measures all stages of change, including action and maintenance, may better capture those who are already participating in behaviors to reduce their diabetes disease risk, which could help further stratify the sample of participants. It is possible that the RTC tool was not robust enough to capture all components of the operationalized definition, or that the definition needs further refining to capture how people move through the stages of change, so using a concurrent measure could help alleviate this possibility. The addition of measuring action and maintenance in future studies could help address the limited variance we saw in this study, as it is possible there were participants already taking action that we did not accurately capture in this study. Furthermore, it appears the operationalized definition could have benefited by the addition of engagement in behavior change, which would add another factor to the RTC tool that could help us understand the RTC of our population better. Furthermore, there was a decrease in RTC from baseline to six months which could be explained by not measuring the action and maintenance stages. It is logical that as individuals are active in a program their cognitions change from readiness to

acting, then maintaining the behaviors. If this is the case, then it makes sense that those who completed this six-month study experienced a decrease on the RTC tool since it only measured precontemplation, contemplation, and preparation. Along with the significant decrease in RTC from baseline to six-months ($p = 0.009$), there were significant differences in weight ($p = 0.009$) and HbA1C ($p = 0.002$), so it is assumed that participants took action through nutrition and physical activity to achieve these results. Perhaps utilizing two tools simultaneously to capture RTC and the later action portions associated with their commitment to change would have offered a more robust analysis and helped us capture how RTC changed over time. Results from both this study and the study by Swan and colleagues (2006) corroborate Dr. DiClemente's comment that people cannot be placed in boxes by measuring RTC (personal communication, June 2021), because if we look at the decrease in RTC over time, we might inaccurately assume that this coincided with a decrease in clinical outcomes. In other words, just because people had high RTC scores at baseline, this did not mean there were not other factors that affected their adherence to the program and ultimately the outcomes they experienced. While we did measure possible covariates that are typically relevant to rural populations, there are likely other factors that affected the results of our study.

Limitations

This was a convenience sample of participants representing one geographic area of Montana, so random selection of participants was not possible, which weakens this study. There were 38 participants at baseline, but there were 28 remaining at the six-month mark. This small sample size is likely the greatest limitation to this study. A post-hoc sample size analysis indicated we should have had 169 people in the study. Logistic regression was the chosen data analysis method to determine if possible, covariates of income and geography modified the

relationship between RTC and the primary outcomes of weight, HbA1C, and blood glucose. However, an assumption of logistic regression is a large sample size, which we did not have, so we reduced the number of possible covariates we put into the logistic regression analysis to include income and geography. With a larger sample, more variables could have been included in the logistic regression to give a more robust look at the possible interaction between the variables. An additional limitation was that all participants were in the same stage of change from the RTC tool. This could have changed with a larger sample or could indicate that the tool needs further modification. While the tool had an acceptable Cronbach's alpha and was validated in a previous study, it is possible that the tool was not sensitive enough to distinguish between participants in different stages. Additionally, the stage cutoffs were pre-determined on the original tool. For the purposes of this study we did not change or re-examine those cut off vlaues. This could have influenced the sensitivity and the ability of the tool to discriminate between stages. While these are limitations to the study, this was a pilot study that provided information on areas for improvement for future research, particularly in using a larger sample size to detect any significant interactions between variables.

Conclusion

This study indicates that there is a not an independent relationship between RTC score and attrition rates and clinical outcomes in a rural sample of prediabetic adults enrolled in the DPP, however, with income and geography included in the analysis, there is a relationship between RTC and attrition. Despite high scores on the RTC tool, 26% of participants dropped out of the program, and because all participants measured into the preparation stage of the TTM, there was no relationship between stage and those who were lost to follow-up. While 93% of participants experienced weight loss, 71% improved HbA1C, and 54% improved blood glucose,

RTC was not associated with these outcomes, nor did ruralness measures of income and geography modify the relationship. This is contradictory to the research that suggests that stage of change as measured by RTC is predictive of outcomes in other chronic disease prevention and treatment programs and that ruralness affects outcomes (Ritchie et al., 2021). These studies were performed in different populations due to lack of research in a rural population with prediabetes, which could have resulted in different outcomes. Future research should include the use of a more sensitive RTC tool and a larger sample size to distinguish between participants in different stages as well as to be able to include more rural covariates such as education, age, and employment status.

Additionally, this study was performed during unprecedented times during the COVID-19 pandemic, so the relationship between RTC, attrition, and clinical outcomes may have been different due to different circumstances people faced. Variables that, retrospectively, would have been interesting to observe would have been stress levels, anxiety and depression, and Zoom fatigue from the digital delivery of the program. Research by Pellegrini et al. (2021) indicated significant increases in stress and decreased mental well-being, both of which were related to individuals being less able to commit time and effort into weight loss efforts. These findings are relevant for rural Montanans who were in stay-at-home orders for four out of the six months of this program. While we do not know the circumstances each individual faced, working from home, loss of income, loss of childcare, having school-aged children at home, along with the anxiety from the pandemic itself could have significantly impacted the results of this study. Considering the results that the rural variables of income and geography did impact attrition, it is logical that those experiencing lower income or who lived in rural geographic areas may have experienced the negative stress effects of COVID-19 disproportionately. Future

research in this area should include a mixed-methods approach so we can gain a deeper understanding of the factors that affect participants' readiness and actions, as qualitative data could have provided valuable insight into these variables that may have been a result of COVID-19.

Information from this pilot study supports evidence from previous research that there may be a difference between readiness and actual engagement in desired behaviors, which can help researchers be more equipped to help participants navigate barriers to change. Recommendations for practice include measuring RTC along with actual engagement in desired behaviors so chronic disease prevention program administrators can better target strategies to help behavior change participants be more successful in achieving their desired health outcomes.

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Tables

Table 1
Frequency Distribution of Demographic Variables of All Participants at Baseline

Variable	N	Proportion
Age (years)		
18 - 59	16	42%
≥60 years	22	58%
Income (US dollars)		
≤ $49,999	13	34%
≥ $50,000	20	53%
Declined	5	13%
Geography (relation to city limits)		
Rural	12	32%
Urban	26	68%
Employment		
Retired	16	42.10%
Unemployed	3	7.90%
Part or full-time	17	44.70%
Unknown	2	5.30%
Education		
(4-year College or higher)	13	34%
Less than 4-year college	25	66%
Gender		
Female	32	84%
Male	6	16%
Ethnic Background		
White	36	95%
Non-white	2	5%

Table 2

Means, Standard Deviations, and P-values of Independent and Dependent Variables

	Mean	Standard Deviation	p-value
RTC (total score)			
B:	27.8	± 2.7	
6mo:	25.6	± 4.1	0.009*
A1C (%)			
B:	5.94	± 0.52	
6mo:	5.65	± 0.37	0.002*
BG (mg/dL)			
B:	106.8	± 29.4	
6mo:	99.5	± 14	0.26
Weight (lbs)			
B:	229.2	± 54.6	
6mo:	206.3	± 60.4	0.009*

Note - * means there was a statistically significant difference between baseline and 6-months

Table 3

Changes within participant scores of independent and dependent variables from baseline to 6 months

	Mean ± SD	t-statistic	p-value
RTC (score)	-1.86 ± 3.6	-2.79	0.009*
A1C (%)	0.26 ± 0.29	3.66	0.002*
BG (mg/dL)	3.57 ± 16.5	1.14	0.26
Weight (lbs)	13.75 ± 25.7	2.8	0.009*

Note - * means there was a statistically significant difference between baseline and 6-months

Table 4

Frequency distribution of those who stayed vs. those lost to follow-up

Age	**18 - 59**	**60+**	***p*-value**	**Sex**	**F**	**M**	***p*-value**
Stayed	40% (11)	60% (17)		Stayed	86% (24)	14% (4)	
LTF	50% (5)	50% (5)	0.7	LTF	80% (8)	20% (2)	0.6
Income	**≤49,999**	**≥50,000**		**Geography**	**Urban**	**Rural**	
Stayed	36% (9)	64% (16)		Stayed	68% (19)	32% (9)	
LTF	50% (4)	50% (4)	0.7	LTF	70% (7)	30% (3)	1
Education	**Some college**	**College or more**		**Race**	**White**	**Non-white**	
Stayed	25% (7)	75% (21)		Stayed	96% (27)	4% (1)	
LTF	60% (6)	40% (4)	0.06	LTF	90% (9)	10% (1)	0.5
RTC	**Score 21 - 28**	**Score 29 - 32**					
Stayed	64% (18)	36% (10)					
LTF	20% (2)	80% (8)	0.03*				

Note – This compares the absolute percentages of those who stayed vs. those who were lost to follow-up. The * denotes a significant finding from Fisher's exact test. The N for each distribution is included in parentheses after each percentage.

Table 5

Maximum Likelihood Estimates and Odds Ratios for Attrition

	Estimate + SE	Wald Chi-S2	Pr > ChiSq	Point Estimate	CI
Total RTC	-1.07	4.2	0.04*	0.34	0.1 - 0.9
Income	1.6	1.3	0.2	5.1	0.3 - 83
Geography	0.03	0	0.97	1	0.1 - 8.5

Note - * means there was a statistically significant relationship

Table 6
Maximum Likelihood Estimates by Outcome Variable

	Blood Glucose			**HbA1C**			**Weight Loss**		
	Estimate	Wald Chi-Sq	Pr > ChiSq	Estimate	Wald Chi-Sq	Pr > ChiSq	Estimate	Wald Chi-Sq	Pr > ChiSq
Total RTC	0.5	3.2	0.07	-0.3	0.6	0.4	0.8	2	0.15
Income	1.1	1.1	0.3	-1.4	0.7	0.4	0.04	0	0.98
Geography	-2.2	3.2	0.07	0.4	0.08	0.8	-12.1	0	0.95

Table 7

Odds Ratios and Confidence Intervals by Outcome

	Point Est.	**95% CI**	
Blood Glucose			
Total RTC	1.6	0.9	2.9
Income	3.1	0.4	25.2
Geography	0.1	0.01	1.2
	Point Est.	**95% CI**	
HbA1C			
Total RTC	0.7	0.3	1.6
Income	0.3	0.01	6.2
Geography	1.4	0.1	15
	Point Est.	**95% CI**	
Weight			
Total RTC	2.2	0.7	6.5
Income	1	0.04	29
Geography	0	0	999

Chapter 5: Conclusion

Type II diabetes is rising at an alarming rate despite evidence-based practices that demonstrate the ability to stop or slow the progression of prediabetes to diabetes. Nutrition and exercise are at the cornerstone of diabetes prevention, and as part of the National Diabetes Prevention Program guidelines, typically result in weight loss that is associated with significant reduction in disease risk (CDC, 2021). Chronic disease researchers have recognized that sustainable behavior change is crucial for achieving successful clinical outcomes, and one of the behavior change models that predominates in the literature is the TTM (Prochaska et al., 2013). Readiness to change is a way for researchers to measure the stage of change from the TTM and is thought to be predictive of outcomes when measured at the beginning of behavior change programs (Arvanitis et al., 2020; Ceccarini et al., 2015; Kaasalainen et al., 2016; Kullgren et al., 2015; Prochaska et al., 2013). While research on RTC and chronic disease prevention exists, it is sparse in relation to diabetes prevention. Additionally, to our knowledge, RTC and its association to clinical outcomes among rural adults in the DPP had not been studied when this study began. Therefore, the overarching purpose of this research was to identify the relationship between RTC and clinical outcomes among rural adults with prediabetes enrolled in the DPP.

There were several steps necessary to answer this question, so the three-article dissertation model was chosen for this dissertation. We followed a rigorous scientific process throughout this research. A literature review on RTC indicated its ubiquitous use across multiple disciplines, so we completed a concept analysis following Rodger's Model of Concept Analyses that resulted in an operational definition of RTC for the first study. Once the operational definition was developed, we were able to distill information from the literature that was relevant to our study. The development of the operational definition not only was crucial to

answering our research question, but helps close a gap in the literature that has led to confusion around the application of RTC. The definition of RTC from this study is the commitment and intention to engage in motivating cognitions and tasks necessary for sustainable behavior change leading to an expected outcome.

The next step in our process was to measure an RTC tool against the newly developed operational definition. The Montana DPP has used an RTC tool of unknown origin for several years, so we validated this tool following Schilling's Model for Instrument Validation, which is a reliable and valid process for instrument development and validation. We also analyzed the psychometrics of the tool to determine internal consistency of the items. There is a perplexing number of RTC tools available, many of which have not been validated or did not follow a rigorous development process. While we did not develop this tool, we followed the same methodology that we would have if we had developed it. Once it was determined that the tool was valid, which is explained in article two, it was utilized in part three of this research, the primary question of interest.

To answer our primary question of the relationship between RTC and clinical outcomes among prediabetics in the DPP, we utilized existing data from a sample of 38 participants after completion of six-months in the program. We examined the relationship between RTC and attrition, then compared RTC scores to the clinical outcomes of blood glucose, HbA1C, and weight among the 28 participants who completed the study through month six. Results from this third and final study considered the relationship between RTC and attrition rates, and RTC with select psychosocial factors as potential covariates on the clinical outcomes of blood glucose, HbA1C, and weight.

Discussion

Specific Aim 1

The first specific aim of this study was to determine the relationship between RTC and attrition rates in a nutrition and physical activity program delivered by the Montana DPP to rural adults with prediabetes.

Hypotheses and Findings

It was hypothesized that higher RTC scores would be associated with lower attrition rates, however, an independent t-test indicated that there was no difference in RTC means between those who dropped and those who stayed in the study, so we refuted this hypothesis. A logistic regression, however, indicated that the two selected psychosocial factors included in the model, income and geography, did modify the relationship such that RTC was significantly associated with attrition. The second hypothesis was that the dropout rate would be higher for individuals in the precontemplation stage than those in the contemplation and preparation stages of the TTM, however, there was no relationship present. We began with 38 participants enrolled in the study and 10 were lost to follow-up, so 28 were included in the final analysis on the relationship between RTC and clinical outcomes. This represented a 26% attrition rate from the program, which is close to the state of Montana average of 30% for digitally delivered programs.

Helitzer et al. (2007) found that there was a significant relationship between stage of change and attrition rates, so our results are in opposition. However, Helitzer and colleagues (2007) also measured for a period of five sessions, while this study was six months with 18 sessions. This different time frame for measurement could have given rise to this discrepancy in

findings between the two studies. Additionally, research by Swan et al. (2006) indicated that there can be a knowledge gap between those who indicate they are ready to make behavioral changes and actually making change. They did not specifically talk about attrition; however, one can extrapolate that measuring into a high stage of change on the RTC tool compared to doing the work to change one's behavior are two different things. Personal communication (June 2021) with Dr. DiClemente, one of the developers of the TTM, indicated that we cannot simply put people in a box when we measure stage as this does not take real life into account. This could be the case with attrition, that while participants think they are ready, they may not actually be ready to complete the tasks to make sustainable change so get discouraged or have extenuating circumstances that result in them dropping from the program

While the above results did not indicate a relationship between RTC and attrition, a logistic regression resulted in the covariates of income and geography significantly modifying this relationship. This does indicate that these measures that commonly affect people who live in rural areas did impact attrition rates. If given the opportunity to redo this study, I would have included these covariates in my hypotheses about attrition. Additionally, a larger sample size would have allowed us to include more covariates that specifically affect rural dwellers, such as education, cultural beliefs, and some psychological measures like anxiety and depression. Anxiety and depression would have been interesting to include particularly in this study that was done during the COVID-19 pandemic as we were in stay-at-home orders in Montana during the first three months of the program.

Ultimately, the results from the logistic regression make sense as people who have lower income or are in more rural areas tend to have less opportunity and less access to programs and healthcare than their urban counterparts (Thomas et al., 2014). Those who dropped actually had

a higher mean RTC score at baseline, so it begs the question about what factors led to them quitting and if any of their reasons were barriers related to the health disparities that often face those in rural areas. While participants could have left for a myriad of reasons, it appears there was a barrier between their perceived high levels of motivation, commitment, and outcome expectancy and following through with the program.

Specific Aim 2

The second specific aim was to better understand the role of RTC in clinical outcomes in the DPP.

Hypotheses and Findings

It was hypothesized that of those who stayed in the program for the full six-month timeframe, those with greater baseline RTC scores would also have greater weight loss, and lower blood glucose and HbA1C at six-months. However, a logistic regression indicated that there was not a significant relationship between RTC and any of these outcomes, although the relationship between RTC and blood glucose did approach significance. Additionally, it was hypothesized that lower income and geographic location would affect the relationship between RTC and the clinical outcomes of weight loss, blood glucose, and HbA1C unfavorably. However, results indicated that neither income nor geographic location modified the relationship between RTC and the measured clinical outcomes. While we did not find statistically significant results, an effect size from Hedges' g (0.65) indicate a moderately strong relationship, suggesting there could be clinical significance.

I think this is an area that particularly may have been impacted by the low sample size, especially because the relationship between RTC and blood glucose approached significance.

Additionally, there was a nearly significant difference between education among those who left compared to those who stayed the duration of the study. While this helps answer attrition more directly, it also provides valuable info about what population of individuals may need more targeted intervention. Ceccarini et al. (2015) indicate that RTC helps researchers place the proper tools in individuals' hands based on stage of change. This confirms what the TTM was created to do – to help people move through change in stages with associated knowledge and tasks (Prochaska et al., 2015). Maybe an analysis of psychosocial factors in unison with baseline RTC scores could prevent attrition and result in more people successfully completing programs that can alter their disease risk and their lives moving forward.

Contribution to Science

While results from this study indicate no significant relationship between RTC and attrition or clinical outcomes in a rural population enrolled in the DPP, there were several important things that came from this research. First, we were able to clarify the concept of RTC, which had previously been left up to interpretation by each research group. There is a large body of literature on RTC, so distilling this down to a clearly defined concept will help future research in this field. Additionally, by validating an RTC tool, we add a tool that has followed the rigorous scientific process that is suggested. While we did not find a significant relationship between RTC and clinical outcomes, we highlight the lack of research around rural health, which necessitates future work. Further, while not the primary research question, there was a significant relationship between RTC and attrition once income and geography were included in the model, which indicates that they do somehow modify the relationship, calling for future research in this area.

Future Research

The greatest limitation of this research was the small sample size. Future research should include a larger sample size, which would also allow for the inclusion of more possible covariates related to rurality. Due to the small sample size, results should be interpreted with caution. For example, RTC as related to the clinical outcome of blood glucose approached significance, and had there been a larger sample we would have been able to examine this relationship, whether significant or not, with greater certainty. However, the small sample size necessitated a limited use of covariates in the logistic regression model, which is why only income and geography were included. We also saw a drop in RTC from baseline to six months, which makes sense that as people move through the TTM their readiness to perform certain behaviors also changes. Future research should include RTC tools that measure the initial RTC score like we did in this study, and concurrently add a tool that measures action and maintenance to better capture the spectrum of where people may start a program. Additionally, utilizing the action and maintenance tool again at six months with the RTC tool used in this study would help researchers better understand how people move through the TTM. A different tool that captures all of the stages could be used in place of using two concurrently. Additionally, researchers should examine the factors that may be correlated with attrition, as we did find that rural covariates did modify the relationship between RTC and attrition.

Recommendations for Practice

While RTC in rural dwellers has not been researched closely and this study did not result in any significant relationship between RTC and clinical outcomes in this study, the body of

literature suggests that RTC is predictive of programmatic outcomes (Arvanitis et al., 2020; Ceccarini et al., 2015; Kaasalainen et al., 2016; Kullgren et al., 2015). These studies had larger sample sizes, and if we had a larger sample, we would have had a more robust analysis that included more possible covariates and would have fit the logistic regression model better.

Research on rural dwellers indicates that they do face unique health disparities and have differences in culture that may result in different health outcomes (Thomas et al., 2014). Even though this study did not indicate significant relationships between RTC and attrition or clinical outcomes, there may be enough dissimilarity between rural and urban populations that this population should be given more attention. Swan et al. (2006) mentioned a gap between knowledge and action. This is similar to readiness and action, that ultimately there could be a difference between readiness and actually beginning, which lends the opportunity for trusted healthcare providers to help patients bridge this gap. Even though we didn't find significant results, the body of literature that suggests that RTC is predictive of outcomes coupled with the knowledge that rural dwellers face disproportionate health disparities should cause us to pause and consider what they may need. A lack of statistically significant results does not mean there may not have been clinically significant relationships. Therefore, future practice should still measure RTC with an emphasis on delivering targeted support, education, and motivation raising based on the stage of individuals. As Dr. DiClemente (personal communication, June 2021) said about not placing people in boxes, maybe RTC is not the only factor we should use to help people work towards sustainable change. A study by Ritchie et al. (2021) looked at the difference between the traditional DPP format and one that encouraged more patient-centered goal setting. They found that those in the traditional DPP had diminished self-efficacy when they did not achieve the goals set forth by the program, but experienced greater success when

they had a role in developing their own goals. Maybe pairing RTC measurement with incorporating self-efficacy building skills such as individual goal setting, in addition to getting people the proper help and resources based on their RTC and unique psychosocial profiles could have a greater impact in preventing type II diabetes. A further practice implication is to consider the effect of extenuating circumstances on outcomes of behavior change programs. This program occurred during the COVID-19 pandemic, which the effects of are unknown and would likely be a completely different study. However, considering life circumstances seems to be a relevant way practitioners can help their patients or clients navigate change so they can persist towards their goals of improving their lives and lessening their risk of chronic disease. Ultimately, with the stakes so high of people losing quality of life and facing significant health challenges, let along the cost of a diabetes diagnosis, these measures could be part of the primary prevention solution to help lessen this burden of disease on individuals and America.

Research Reflection

I learned an incredible amount during this dissertation work. Likely the greatest takeaway for me is the importance of following the scientific process in every aspect of my future research. Everything I did was guided by a scientific process, even if that meant major revision because I did not follow the process from the beginning. I have also learned that research often leads to more questions. For example, what would have happened if this was not during COVID and participants could have met face-to-face? I learned the importance of sample size and selecting the correct statistical analyses not only for what is being measured, but also for said sample size. I wonder what would have happened if we had a larger sample size, and dream of what it would have been like if we could have done this study across the whole state. The literature review process left me dumbfounded with how much health disparities tend to impact

certain populations and fuels my fire to continue my work in rural public health to help people gain access to care and services they need, which is an important policy implication of this work. I learned an endless amount about how much work goes into scholarly work, and I know I have just scratched the surface. Finally, while this is cliché, I have learned more about myself the past four years than I ever thought possible and am proud of myself for persisting despite facing several adverse circumstances that tested my grit and determination . I'm grateful for the opportunity or a lifetime to do this work and for all the guidance along the way!

Appendix A: IRB Approval

Office of Human Subjects Protection

TO: Haifa Abou Samra, Katie Wagner,
School of Health Sciences

FROM: Human Subjects Protection Program

DATE: Sep 6, 2021 12:08:08 AM CDT

RE: Impending Expiration of IRB Approval

STUDY #: IRB-20-234

STUDY TITLE: Readiness to Change in Rural Adults Who Are at High Risk for Diabetes

EXPIRATION DATE OF APPROVAL: Nov 5, 2021

The IRB approval for the above-referenced study will expire on Nov 5, 2021. As Principal Investigator, you must apply for RENEWAL of IRB approval via Cayuse IRB Cayuse IRB if you plan to continue any study activity beyond the expiration date, allowing ample time for review before the expiration date. If all study activity has been completed, please submit for CLOSURE with the IRB.

Please note that the HHS regulations at 45 CFR part 46 do not make provisions for any grace period extending the conduct of research beyond the expiration date. If the IRB approval of this study is not renewed, **all research activities must STOP on Nov 5, 2021**, except where doing so would jeopardize the welfare of the human subjects (in this case contact the IRB IMMEDIATELY). In addition, any lapse in approval could negatively impact funding.

Please disregard this notice if you have already submitted your renewal materials.

Thank you in advance for your immediate attention to this matter.

Office of Human Subjects Protection
414 E Clark, Vermillion, SD
605-658-3743
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