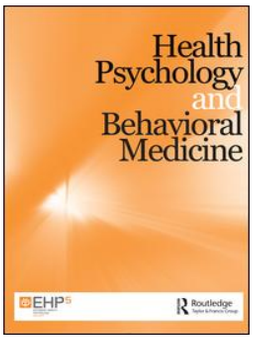

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Development and pilot testing of a novel behavioral intervention for adults with type 2 diabetes using intervention mapping

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ABSTRACT

Purpose: A healthy diet and consistent physical activity (PA) form the foundation for effective self-management in adults with type 2 diabetes mellitus (T2DM). Behavioral interventions, which target diet and PA, can facilitate effective diabetes self-management practices. Greater clarity regarding the 'active ingredients' incorporated into behavioral interventions is needed to inform the evidence base about effective intervention techniques to advance behavioral theories and to improve clinical practice. The use of intervention mapping (IM) to develop a novel diabetes intervention to increase consumption of low glycemic index (GI) foods and to increase moderate-to-vigorous intensity PA is presented.

Methods: Determinants from self-regulation and the Health Action Process Approach theoretical framework formed the foundation of the intervention. The IM taxonomy of behavior change methods and strategies from Hope Therapy (e.g. goal maps) were used to guide techniques for changing selected theoretical determinants of behavior. A pilot study of the intervention among adults with T2DM ($n = 12$) was conducted using a pre-/post-test design to evaluate intervention components and participant acceptability.

Results: Participants attended a mean (±SD) of 8 (±1.4) of the 10 weekly 90-minute, group-based sessions. The magnitude of effect was moderate ($d > 0.50$) for the change in behavioral intentions, action control, and action and coping planning for engaging in PA and large ($d > 0.80$) for the change in action self-efficacy and action and coping planning for eating low GI foods post-intervention.

Conclusions: Greater emphasis on value-based decision-making, the goal mapping process, and successively progressive exercise goals should be included in future versions of the intervention. Based on pilot testing, a larger randomized controlled trial that incorporates these intervention modifications is warranted and the modified intervention has a greater likelihood for success.

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Introduction

The prevalence of type 2 diabetes mellitus (T2DM) continues to increase in the U.S. population in both sexes and in every age and racial/ethnic group (Menke, Casagrande, Geiss, & Cowie, 2015). Given its prevalence and quality-of-life burden (Zhuo et al., 2014), there is a great need for better treatment options. Regular physical activity (PA) and consumption of a healthy diet form the cornerstones of effective diabetes self-management (American Diabetes Association, 2017). Including a low glycemic index (GI), low glycemic load dietary component within the context of a healthy diet may reduce the comorbidities associated with T2DM (Augustin et al., 2015).

Changing health behaviors, such as diet and PA, is challenging. There is a need to develop and implement effective health behavior change interventions with well explicated and testable mechanisms of change. Michie and Johnston (2012) recently called for greater clarity regarding the 'active ingredients' (i.e. behavior change techniques) and links between intervention components and theoretical mechanisms of change. Intervention mapping (IM) provides a framework for linking behavior change techniques to theoretical mechanisms of change during intervention planning, implementation, and evaluation (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011).

Comprehensively describing interventions, in combination with evaluative feasibility and impact studies, will provide the evidence base to design new interventions, advance theories of behavior change, and ultimately improve practice. For intervention developers, an intervention is more than the end product; it is a complex process that requires a multitude of decisions to be made during development (Brendryen, Kraft, & Schaalma, 2010). The rationale for each decision represents valuable knowledge for the field and a standardized reporting process will aid knowledge creation.

To this end, IM provides a framework for effective decision-making in intervention development, implementation, and evaluation based on theory, empirical evidence, and additional research (Bartholomew et al., 2011). IM includes six iterative steps: (1) conduct a needs assessment; (2) create matrices of change objectives; (3) select theory-based intervention methods and practical applications; (4) organize methods and applications into an intervention program; (5) plan for program adoption, implementation, and sustainability; and (6) generate an evaluation plan. Each step builds on the preceding step providing intervention designers with a logical process. In the past, interventionists used IM to develop nutrition, PA, and diabetes prevention interventions (Cullen, Bartholomew, Parcel, & Kok, 1998; Elsman et al., 2014; Gillison et al., 2012; Van Stralen et al., 2008). However, we know of no other intervention that used the IM framework to develop an intervention for adults with T2DM. Yet, patients with T2DM report difficulty adhering to diet and PA self-management behaviors as components of the diabetes self-management regimen (Ary, Toobert, Wilson, & Glasgow, 1986).

Therefore, the purpose of this paper is to describe the development of the Pathways Diabetes Intervention and present feasibility results using the IM framework. The goals of the Pathways intervention were to increase consumption of low GI foods and increase PA based on prior research (Gutschall, Miller, Mitchell, & Lawrence, 2009; Miller, Gutschall, & Mitchell, 2009; Miller, Headings, Peyrot, & Nagaraja, 2011). Because the Pathways intervention was informed by prior formative (Davis & Miller, 2006) and intervention research, a separate needs assessment (IM step 1) was not conducted. Instead, we

focused on the development of a novel intervention and IM steps 2–4 are presented here to bridge the link between theory and intervention programming. Results from a feasibility study to evaluate program components and participant acceptability of the intervention also are reported in preparation for broader program implementation (IM step 5) and efficacy/effectiveness evaluation (IM step 6).

Methods

IM step 2: matrix of change objectives

Step 2 involves stating the specific behaviors to change (i.e. program goals), sub-behaviors to target (i.e. performance objectives) to achieve change, and mechanisms that produce those behaviors (i.e. determinants or mediators). An essential tool for IM is the matrix of change objectives, where the matrix is populated with information that program developers provide regarding performance and change objectives (Bartholomew et al., 2011). Change objectives target the mechanisms by which program participants achieve performance objectives and specify what must be learned or changed. Performance objectives state exactly what program participants need to do (or perform) to accomplish program goals. For example, an increase in perceived confidence or self-efficacy (SE, determinant) to initiate an action plan (performance objective) to increase consumption of low GI foods (program goal) aligns a theoretical determinant with a performance objective and a program goal.

The program goals and performance objectives for the Pathways intervention included increasing consumption of low GI foods and level of PA. In order to achieve these program goals, study participants needed to identify their current level of performance of these behaviors (e.g. consume 1 serving/day of a low GI food) compared to the goal level (consume 4 servings/day) and determine if a discrepancy exists (sample performance objectives; see column 1 in Table 1). The GI goal included substituting low GI foods (a GI value <56 on a 100-point scale with pure glucose equivalent to 100) for higher GI foods. It is beyond the scope of this paper to review the concept of GI and its potential health benefits (for review see Barclay et al., 2008; Chiu et al., 2011; Wang, Xia, Zhao, & Zhang, 2015). Briefly, consumption of carbohydrate-containing foods variably affects the post-prandial plasma glucose response, and GI classifies foods according to that response. Glycemic load is GI adjusted for the quantity of food consumed (Augustin et al., 2015). In our previous research, participation in a behavioral intervention increased consumption of low GI foods by an average of 1.79 (±0.53 SE) servings (Miller et al., 2011). In an attempt to increase gains during the intervention phase for the current study, we established the program goal of substituting ≥3 servings/day of low GI foods for higher GI foods beyond the number of low GI servings consumed at one's personal baseline. For example, if the person consumed 3 servings/day on average at baseline, the program goal for an individual participant was set at ≥6 low GI servings/day. One approach to goal achievement is to substitute 1 lower for 1 higher GI food at each of 3 meals (but alternate approaches also are possible, including snack substitutions). Thus, ≥3 substitutions per day seemed realistic and practical as a dietary goal. For PA, the American Diabetes Association recommends adults with T2DM achieve ≥150 minutes/week of moderate-to-vigorous intensity PA (Colberg et al., 2016). Therefore, the Pathways intervention included a dietary and ≥150 minutes/week PA goal as the target behaviors.

Table 1. Intervention matrix of performance and change objectives for the Pathways Diabetes Intervention.

	Personal Determinants							
Performance objective (PO)	Risk perception	Knowledge	Outcome expectancies	Self-efficacy	Agency	Values	Intention	Action Control
PO 1. Identify current LGI foods consumed, PA behaviors and glucose patterns	State the relation among food and PA to health	Identify type and quantity of LGI foods commonly consumed; identify current PA behaviors	Expect food, PA and glucose self-monitoring will enable self-observation and awareness	Increase confidence in identifying LGI foods, portion sizes, and greater PA, and in monitoring behaviors	Realize change begins with awareness and acceptance of where you are and starting from that point	Clarify personal values related to health and well-being	Set intention to self-observe and self-monitor	
PO 2. Compare current behavior to behavioral goals	Recognize excess HGI foods, inadequate level of PA, and out-of-range glucose values	State goals for LGI servings and minutes of PA; identify high-risk situations for over-eating and inactivity; identify food cues and sedentary behaviors			Express that hope is a learned way of thinking about goal pursuit		Agree that goal pathways develop strategies for goal pursuit	Appraise the situation as one that is relevant to personal goals
PO 3. Determine if discrepancies exist	Realize current behavior(s) increase risk and vulnerability for T2DM-related comorbidity		Acknowledge that discrepancies are normal	Use incremental tasks to narrow discrepancies; obtain verbal persuasion from facilitator			Set intention to reduce gap b/t current behaviors and recommended behaviors	
PO 4. Create a plan to meet program goals		Demonstrate how to determine the GI value and portions of food, appropriate exercise routine, and stretching postures	Expect LGI food intake and increased PA will improve health	Increase confidence in initiating action plan (i.e. agency and action SE); imagine success	Commit to achieve goal; realize goal attainment occurs best through positive self-care and a healthy lifestyle	Internalize values for change; align goals with core values; become aware of in-the-moment decision-making consistent (or not) with values	Set SMART, 'stretch' goals consistent with core values; identify cues to action	

PO 5. Self-monitor behaviors during goal pursuit		Explain how to properly use glucose monitoring device and self-monitoring logs	Expect monitoring to provide useful information and not be too time-consuming	Express confidence in using monitoring device and logs	Gain satisfaction in the journey; reinforce goal progress	Commit to self-regulation of behaviors; choose value-based decision-making		Perform monitoring with optimism; keep goal intentions salient
PO 6. Evaluate progress toward goal attainment		Identify reasonable progress outcomes	Expect to make gradual progress	Express confidence in persevering toward goals and prioritizing goals	Remind self that setbacks happen; recall when goals were attained despite obstacles; celebrate goal progress and success		Set intention to overcome obstacles and resolve goal conflicts	Agree that goal attainment requires deliberate effort
PO 7. Assess self-reaction regarding progress	Acknowledge lapses are common but increase vulnerability for relapse	Identify events which trigger a slip (e.g. when pursuing challenging goals); realize a lapse does not have to become a relapse; recognize that all information is helpful feedback	Feel positive about: lower glucose, more energy, achieving goals, praise from others	Visualize overcoming obstacles and resisting temptations; attribute failures externally and achievements internally (i.e. coping SE)	Experience satisfaction in goal attainment; maintain flexible thought to continue on the path to goal attainment	Acknowledge the information learned from slips; recognize that values serve as a compass in goal pursuit; commit to higher-order life values	Strengthen resolve to achieve goals	Focus on what is achieved rather than failure
PO 8. Modify diet and PA goals, as needed	Acknowledge sustained risk for T2DM-related comorbidity		Expect to be more successful in goal striving with information gained from self-evaluation	Express confidence in continued goal striving and recovery from setbacks (i.e. recovery SE); continue to exert effort and persevere	Realize setbacks do not have to result in goal abandonment; create alternate paths to goal attainment	Re-align goals with values, as needed	Set intention for a coping plan	

Note: LGI: low glycemic index foods; PA: physical activity; HGI: high glycemic index; T2DM: type 2 diabetes mellitus.

Theories of self-regulation provide strategies for developing new habits and served as the foundation for the identification of performance objectives for the current study. Self-regulation refers to the monitoring and modulation of thoughts, feelings, and behaviors to be consistent with desired ends (Carver & Scheier, 1998; Mann, de Ridder, & Fujita, 2013). Behavior change in the current environment that many adults with T2DM are confronted with requires prioritizing health concerns in the face of omnipresent temptation. Self-regulation is thus essential in this context. Following prior research (Gutschall et al., 2009; Miller et al., 2009, 2011), we used the Health Action Process Approach (HAPA) to guide intervention development. Critically, the Pathways intervention also incorporated novel insights and intervention techniques emerging from self-regulation research in health and social psychology (Mann et al., 2013; Rand & Cheavens, 2009). A brief overview of HAPA and self-regulation determinants chosen is described below.

Health Action Process Approach

The HAPA differentiates between motivation to change behavior leading to an intention to change and actively pursuing behavior change (Schwarzer, 1999, 2008). An intention to act is based on risk perceptions, outcome expectancies, and perceived SE. Risk perception assesses the perceived vulnerability for poor health outcomes (e.g. T2DM-related comorbidity). Although risk awareness is not a powerful determinant of behavior, it can lead to deliberation about behavior change (Sniehotta, Scholz, & Schwarzer, 2005a). Outcome expectancies represent beliefs about the positive and negative outcomes of the target behavior and contribute to forming an intention to change. SE represents belief in one's capability to perform the behavior. In HAPA, action SE operates in concert with positive outcome expectancies and risk perception to form an intention to act.

Once an intention to act is formed, planning is needed to bridge the gap between an intention to act and acting on the behavior. However, successful behavior change requires not only getting started but also persisting and restarting after setbacks occur until the goal is attained. SE remains influential after an intention has been formed until the new behavior becomes habitual, and HAPA identifies three types of SE beliefs. Action SE refers to one's confidence in being capable of performing a difficult or novel behavior. Coping SE describes optimistic beliefs about one's capability to sustain a behavior regardless of obstacles encountered. Similarly, recovery SE describes individuals' conviction to get back on track after an interruption or being derailed. Individuals with a high degree of recovery SE trust their ability to regain control after a setback or failure. Finally, action control, a separate concept, facilitates intention initiation and maintenance by becoming aware of the behavioral standards one is trying to achieve, self-monitoring behavior during goal striving, and regulating effort to reduce the discrepancy between behavioral standards and actual behavior (Sniehotta, Nagy, Scholz, & Schwarzer, 2006). Action control is hypothesized to be the most proximal volitional predictor of behavior (Sniehotta et al., 2005a).

Agency and values in the self-regulation of behavior

Self-regulation is particularly important in the context of self-control dilemmas (i.e. situations that present immediate rewards yet undermine more valuable, longer-term goals; Ainslie, 1975; Fujita, 2011). HAPA is largely silent about people's dynamic shifts in

motivation from situation to situation and how behavior change goals can compete with alternate goals (Mann et al., 2013). Consider, for example, a participant presented with a favorite pasta dish. The pasta dish is tempting and activates a hedonic eating goal. This temptation may in turn weaken the resolve to maintain another goal of eating a healthy diet (Stroebe, van Koningsbruggen, Papies, & Aarts, 2013). Successful behavior change requires prioritizing healthy eating goals over these competing and short-term hedonic eating goals on a consistent basis.

Self-regulation research acknowledges that multiple goals operate simultaneously and strategies for maintaining attention to and success toward behavior change goals in the face of competing goals are available. A key strategy is integrating the role of construal in resolving self-control conflicts (Fujita & Carnevale, 2012; Metcalfe & Mischel, 1999). The term 'construal' refers to people's subjective understanding of a given event. For example, construing a piece of cake as a 'tasty snack' may lead people to experience stronger impulses to consume the cake. By contrast, construing the same cake as 'a fattening indulgence' should reduce those impulses and motivate restraint. Research suggests that construals of temptations that focus on their concrete consumatory features promote self-control failure, whereas construals that focus on more abstract goal- and value-relevant features promotes self-control success (Fujita & Carnevale, 2012; Metcalfe & Mischel, 1999).

Linking goals to broader values can help resolve self-control conflicts. For example, someone working toward increasing PA, would be encouraged to identify and call to mind values that would be well-served by progress on this goal (e.g. life unencumbered by disability and more time with loved ones). Re-construing temptations (e.g. omit exercise to watch television) in terms of values actively reminds people why they want to practice restraint in pursuit of the more valued goal. By linking values to self-control conflicts, the Pathways intervention incorporated a determinant not explicitly addressed in HAPA.

Beyond improving self-control, values address another key factor in behavior change (Doi, Yokomitsu, & Sakano, 2016). That is, even if people are certain they can perform a behavior, they may have no compelling reason to do so. Various factors, such as competing priorities, environmental and social pressures, and habitual patterns of behavior, can waylay even the strongest intention to act. Reminders of one's values and use of positive agentic thinking may influence the attractiveness of behavior change goals and, consequently, the motivation to engage in and continue to strive toward those goals (Eccles & Wigfield, 2002). Effortful choices are not likely to be made unless one has clearly linked behavioral choices to agency and goals that are consistent with personal values. The relative value attached to a goal should influence the likelihood that effort will continue to be exerted. Positive agentic thinking provides the motivation for overcoming obstacles during ongoing goal pursuit.

Thus, the Pathways intervention is the first intervention, to our knowledge, grounded in this integrative theoretical approach that incorporated determinants from HAPA and self-regulation more broadly. To inform the determinants, we incorporated theoretical propositions from HAPA and self-regulation, as discussed above. Finally, change objectives were generated at the intersection between performance objectives and determinants (see Table 1). The resulting matrix became the focal point for the integration of theory with the desired behavior changes.

IM step 3: theory-based methods and practical strategies

IM step 3 involved the selection of theoretical methods and practical strategies for addressing change objectives. Taxonomies of behavior change techniques or methods are general techniques or processes demonstrated to change one or more theoretical determinant of behavior (Kok et al., 2016). Practical strategies or applications are translations of theory-based methods for practical use specifically designed to meet the needs of the target population in the environmental context in which the intervention will be delivered with consideration for the delivery method (e.g. face-to-face, internet, telephone). Translating methods into practical applications required a sufficient understanding of the parameters under which the theoretical process is or is not effective. For example, goal setting can be an effective method to promote change but requires the goal to be specific, sufficiently challenging, and action oriented (Locke & Latham, 1990). The taxonomy of behavior change methods developed by Kok et al. (2016) was used for the Pathways intervention (see Table 2). Basic methods designed for intra-individual change, which may be applied to almost any determinant, are presented first. Methods designed to change specific determinants follow with the definitions used in the IM taxonomy (Kok et al., 2016). With the taxonomy, the IM process resulted in a toolbox where methods that appropriately fit within the intervention context were selected.

Furthermore, methods drawn from Hope Therapy were included in the intervention to address theoretical drivers of program goals to achieve behavior change according to self-regulation. Hope Therapy was developed as an application building on the theoretical and empirical literature suggesting that hope is strongly associated with self-regulation, primarily as demonstrated through optimal goal-setting behaviors and goal outcomes (e.g. Snyder, 1994; Snyder et al., 1996). The therapy is broadly defined as a set of intervention strategies aimed at improving goal-setting strategies (i.e. setting specific goals with measurable endpoints, anticipating goal-relevant obstacles), increasing pathways thinking (i.e. generating workable routes to important goals) and agency thinking (i.e. generating and maintaining goal-relevant momentum and motivation) (Cheavens, Feldman, Gum, Michael, & Snyder, 2006; Feldman & Dreher, 2012; Thornton et al., 2014). An example of a group activity that is drawn from Hope Therapy is the 'goal maps' activity (Cheavens et al., 2006). In this task, participants graphically depict program goals, their current position relative to the program goal, and the various ways (or 'pathways') that could link current state to the desired goal state. Participants also anticipate and depict obstacles to goal attainment and actively plan alternate pathways to overcome or bypass these obstacles.

For example, someone with a goal of increasing PA to 150 minutes/week, would describe her current PA behavior (e.g. walk the dog once/day for 10 minutes) on the goal map. Then, the PA goal (e.g. exercise $\geq$30 minutes/day 5 days/week), and the various pathways that would move her from her current behavior to her goal behavior (e.g. walk the dog twice/day, walk with a co-worker at work for 20 minutes during lunch, and join a 60-minute exercise class at the recreation center on Sundays) would be depicted on the map. The goal map includes anticipated obstacles (e.g. co-worker takes a vacation) and ways to overcome each obstacle (e.g. download interesting podcasts for the lunch walk during those two weeks).

This goal mapping exercise not only allows participants to think about and set appropriate goals, but it also helps them plan strategies for goal attainment and provides a visual metric for tracking goal progress. Completing the goal mapping exercise is a form of

Table 2. Intervention matrix and definition of behavior change methods and practical applications for each behavioral determinant in the Pathways Diabetes Intervention.

Determinant	Method	Method definition[a]	Practical application
General	Participation	Assure high level engagement of participants	Group-based intervention; participants divide into small groups or pairs for 'hands on' activities and goal-setting activities
	Belief selection	Use messages designed to strengthen positive beliefs, weaken negative beliefs, and introduce new beliefs	Explain benefits of LGI foods compared to higher GI foods; review benefits of PA and ill effects of sedentary behaviors
	Active learning	Encourage learning from goal-driven and activity-based experience	Include goal-based activities
	Individualization	Provide opportunities for learners to have questions answered or instructions paced according to their individual progress	Questions addressed during group sessions; individual feedback provided on self-monitoring records; facilitator contact information provided for questions/help needed between group sessions
	Feedback	Give information regarding the extent to which individuals are accomplishing learning or performance, or the extent to which performance is having an impact	Group facilitator provides feedback on self-monitoring records and weekly self-set goal selection; identifies patterns in glucose responses pre- and post-prandially in self-monitoring records
Risk Perception	Consciousness raising	Provide information, feedback, or confrontation about the causes, consequences, and alternatives for a problem or a problem behavior	Discuss glucose targets before and after eating; compare individual values from self-monitoring to target values; help identify relations between food intake, PA and glucose response
	Personalize risk	Provide information about personal costs or risk of action or inaction with respect to the target behavior	Explain relation between A1c values and diabetes comorbidities; self-monitor blood glucose pre- and post-prandially and compare values to targets
	Self-affirmation	Increase self-image by having people elaborate on their relevant values or desirable characteristics	Elaborate core values, especially health values
Knowledge	Chunking	Use stimulus patterns that may be made up of parts but that one perceives as a whole	Organize new information into sub-units to minimize 'information overload'; include concept maps regarding carbohydrates and GI; summarize key concepts via text boxes in participant manual
	Advance organizers	Present an overview of the material that enables a learner to activate relevant schemas so that new material can be associated	Include weekly session objectives and outline of topics in participant manual
	Discussion	Encourage consideration of a topic in open informal debate	Include weekly group review and discussion of topics and activities
	Elaboration	Stimulate the learner to add meaning to the information that is processed	Include 'hands on' activities to apply principles discussed; integrate new concepts with prior concepts; highlight recommended behaviors via text boxes in participant manual
Outcome expectancies	Self-reevaluation	Encourage combining both cognitive and affective assessments of one's self-image with and without an unhealthy behavior	Review self-monitoring records to assess goal progress
	Direct experience	Encourage knowledge through the interpretation of experience	Monitor and record pre- and post-prandial glucose values; identify glucose patterns in relation to food

(*Continued*)

Table 2. Continued.

Determinant	Method	Method definition[a]	Practical application
			and PA; measure food portions during food label session; select LGI foods at supermarket; include group walk during PA session
Self-efficacy	Verbal persuasion	Use messages to suggest possession of certain capabilities	Group facilitator encourages goal initiation and striving each week
	Modeling	Provide an appropriate model being reinforced for the desired action	Supermarket session to demonstrate shopping for LGI foods; include walking and demonstrate stretching during PA session; participants share 'lessons learned' during goal striving
	Guided practice	Prompt rehearsal and repetition of behavior, discuss experience, and provide feedback	Provide LGI substitutions for high GI foods; provide ideas for: grocery shopping lists, household pantry, snacks and meals; demonstrate recipe modification; provide LGI recipes; identify LGI foods when dining out
	Enactive mastery experience	Provide increasingly challenging tasks	Encourage incremental goal setting each week
Agency	Reattribution training	Help people reinterpret previous failures in terms of unstable attributions and previous successes in terms of stable attributions	Recognize that slips happen; learn from prior slips
	Improve physical and emotional states	Prompt interpretation of enhancement or reduction of physiological and affective states to judge own capabilities	Develop strategies for preventing hypoglycemia and positive self-talk
Values	Self-reevaluation	Encourage combining both cognitive and affective assessments of one's self-image with and without an unhealthy behavior	Elaborate core values; align goals and actions with values
Intention	Goal setting	Prompt planning regarding what to do to achieve target behavior	Establish weekly SMART, stretch goals via goal maps
	Action planning	Specify when, where, what, and how to achieve the goal	Plan what, when, where, how, and how often for each goal behavior; place monitoring tools in appropriate location(s) as cues to monitor; identify preparatory behaviors
	Coping planning	Prompt list of potential barriers and ways to overcome them	Plan how to overcome obstacles to goals via goal maps
Action control	Self-monitoring of behavior(s)	Prompt record keeping of specified behavior(s)	Plan day, time and location to monitor glucose; plan day, time and location to record glucose values, food intake, and PA in logs

Note: LGI: low glycemic index; GI: glycemic index; PA: physical activity.
[a]Kok et al. (2016).

planning (included in HAPA) and may boost action and coping SE simultaneously by providing clear evidence of the multiple means to the same end and how obstacles can be overcome using a variety of approaches. Furthermore, self-monitoring PA behaviors during the week fulfills a component of action control in HAPA.

IM step 4: program planning

Following development of intervention methods and strategies, the complete Pathways intervention was developed. An in-person, group-based delivery method was chosen

Table 3. Content topics presented during weekly intervention sessions.

Week	Topics discussed
1	Program overview and program goals; impact of GI on health; guidelines for effective self-monitoring
2	Reading food labels and portion control; impact of GI and glycemic load on post-prandial glucose; self-monitoring goals reviewed
3	How food processing and preparation affect GI values; SMART goals defined and illustrated
4	Using the GI in menu planning and grocery shopping; goal mapping introduced
5	Impact of physical and mental energy on motivation; agentic thinking and positive self-talk
6	PA for effective diabetes self-management with a brief walk
7	Supermarket tour and recipe modification
8	Selecting low GI foods when dining out; overcoming obstacles to lifestyle change and goal mapping
9	Value identification and recovering from setbacks
10	Program review of key points; goal mapping for maintaining lifestyle change

based on previous formative research (Davis & Miller, 2006). Also, group-based approaches provide social interaction and support that is lacking when interventions are delivered individually. Content was organized and sequenced into ten 90-minute, weekly group sessions based on learning principles to avoid presenting too many new concepts at once (Driscoll, 1994) and theoretical principles of incremental skill-building for mastery. Table 3 provides an overview of the weekly intervention content.

Participants received material and completed activities to assist the skill-building and self-monitoring process. Each participant received: a written manual, which explained all topics discussed during each intervention session; logs for self-monitoring GI food values, minutes spent in PA, and pre- and post-prandial glucose values; a book with GI values to facilitate self-monitoring (Brand-Miller et al., 2014), sample low GI meal plans at four calorie levels, and low GI recipes. Self-selected SMART goals (i.e. specific, measurable, attainable, relevant, timely) were established by participants each week to help meet program goals. Goal specificity was emphasized as participants were asked to indicate the day, time, and location for performing self-monitoring and recording activities and PA behaviors. Goal maps were created during three of the sessions (see Table 3).

Intervention sessions opened with a discussion of participant experiences encountered in goal striving and self-monitoring during the previous week. New material was then presented, followed by application of the content and behavioral tools through an individual or small group activity (see Table 2). For example, session 2 included measuring portions of certain foods (e.g. cereal) to gain a better understanding of the quantity of food and carbohydrate consumed. This activity was designed to increase awareness of food portions for self-regulation purposes.

Participants were encouraged to self-monitor dietary changes and PA by recording everything they ate and drank (and the associated GI values) and minutes spent in daily PA. They also were asked to record pre- and post-prandial glucose values for at least three meals each week. We suggested that they rotate the meal selected for self-monitoring (e.g. breakfast on day 1, lunch on day 2, dinner on day 3) to gain a better understanding of glucose responses following food consumption (and not just fasting values) and to reduce the burden and cost associated with glucose monitoring. Intervention sessions for the pilot study were facilitated by a registered dietitian and a graduate student in psychology who were trained in the intervention protocol. Self-monitoring records were reviewed weekly by the dietitian, and individual, written feedback was provided.

Preliminary IM step 5: pilot test of the intervention

Following development of the Pathways intervention, we conducted a small feasibility study with adults diagnosed with T2DM ≥1 year using a pretest-posttest design. These individuals participated in the 10-week intervention and completed instruments to assess perceived disease risk, HAPA determinants, hope, and self-control measures. Each instrument and subscale are briefly described below, and subscale scores were determined for evaluation.

High-risk perception, according to HAPA, influences one's intention to engage in behavioral change (Schwarzer, 2008). The Risk Perception Survey-Diabetes Mellitus assessed perceived risk for diabetes complications and other personal risks, such as other diseases and environmental factors. The survey includes five subscales: (1) personal control over developing diabetes complications; (2) optimistic bias regarding the belief that one is less likely to develop complications than other people; (3) personal risk regarding perceived risk for nine other diseases (e.g. kidney failure); (4) comparative environmental risk which compares the perceived risk of nine potential hazards in the environment (e.g. pesticides); and (5) degree of worry related to developing diabetes complications. The composite score had adequate internal consistency (Cronbach $\alpha = 0.85$) among a diverse sample of people with diabetes previously (Walker et al., 2007).

In addition to one's risk perception, outcome expectancies and SE influence one's intention to change behavior, according to HAPA. For PA in the feasibility study, items queried how likely one would be to engage in regular PA within the next month with regular PA defined as being active at least 5 times/week for at least 30 minutes each time, consistent with the Pathways goal. Both positive and negative outcome expectancies and SE statements (e.g. How likely is it that you will get regular physical activity within the next month when you have other demands?) developed for people with diabetes were administered using a 5-point response format (Plotnikoff, Lippke, Courneya, Birkett, & Sigal, 2008). Intention regarding likelihood of being regularly physically active within the next month was assessed with 1-item ranging from 0% to 100% (Plotnikoff, Blanchard, Hotz, & Rhodes, 2001). Action SE for PA was assessed via a separate instrument using 13 items validated previously among people with diabetes (Plotnikoff et al., 2001, 2008).

While outcome expectancies and risk perception influence motivation to set an intention to act according to HAPA, SE remains influential before and after an intention to act has been established. Coping (e.g. I am confident that I can be physically active even if it is difficult for me) and recovery (e.g. I am confident that I can resume my physical activity even if I was not active for some time) SE items used previously (Parschau et al., 2014; Schwarzer, Ziegelmann, Luszczynska, & Scholz, 2008) were administered to assess confidence in dealing with obstacles to change. The self-regulatory component of action control (e.g. I can control my physical activity when the weather is bad), action planning, and coping planning items from previous research also were administered (Parschau et al., 2014; Schwarzer, Lippke, & Luszczynska, 2011). Response options included a 5-point format ranging from strongly disagree to strongly agree.

Prior research has not targeted consumption of low GI foods using a HAPA framework. Thus, HAPA-related determinants were assessed in the feasibility study using items similar to the PA items and other items patterned from prior research (Parschau et al., 2014; Sniehotta, Schwarzer, Scholz, & Schuz, 2005b). Outcome expectancies addressed

potentially positive results from eating low GI foods (e.g. If I eat low glycemic index foods, my blood sugar will improve), and intentions addressed key behaviors targeted during the intervention (e.g. I intend to prepare some low glycemic index foods at home). A second instrument assessed coping and recovery SE, the self-regulatory component of action control, and action and coping planning for incorporating low GI foods into the diet. Response options ranged from strongly disagree to strongly agree. An instrument developed and validated previously to assess action SE for eating low GI foods also was administered (Miller, Gutschall, & Lawrence, 2007).

The State Hope Scale was administered to assess pathways (i.e. perceived ability to generate routes to goals) and agentic (i.e. the perceived ability to generate mental energy to successfully achieve goals) thinking in a given moment, indicating one's current goal-directed thinking (Snyder et al., 1996). Three items assess pathways thinking and three items assess agentic thinking for achieving goals with response options ranging from 1 = 'definitely false' to 8 = 'definitely true;' higher scores represent more hopeful thinking. Previous research found the instrument possesses construct, convergent, and discriminant validity and high internal consistency (Snyder et al., 1996).

Self-control (i.e. the ability to prioritize larger-later over smaller-immediate rewards) also was assessed (Ainslie, 1975; Fujita, 2011; Mischel, Shoda, & Rodriquez, 1989). The brief Self-Control Scale is a self-report trait measure with adequate internal consistency and test-retest reliability; it has been used to predict a broad range of positive outcomes (e.g. less binge eating, better interpersonal skills, more optimal emotional responses) previously (Tangney, Baumeister, & Boone, 2004). Response options range from 1 = 'very much like me' to 5 = 'not at all like me.' The scale was administered as an exploratory measure to determine the impact of a brief intervention on self-control as a means of altering self-control success or failure.

Consistent with the IM process, a pilot test of the intervention was conducted to help refine the intervention and study procedures for a larger trial (Leon, Davis, & Kraemer, 2011). Specifically, we wanted to assess the acceptability, sequence, and flow of session topics and activities, assess the usability of study instruments, and determine participant satisfaction with intervention delivery and duration. Instruments were self-administered pre- and post-intervention for participants to complete at home at their convenience. Twelve participants (10 female) completed the pilot feasibility study (mean (±SD) age 53.9 (±8.7) years with a median duration of T2DM of 6.5 years). The study was approved by the Institutional Review Board at the sponsoring university, and participants provided written informed consent.

Results

Participants attended a mean (±SD) of 8 (±1.4) sessions. Table 4 provides baseline scores for each determinant, the change in score from pre- to post-intervention, and effect size estimations. Because this was a feasibility test of the intervention, the study was not powered for hypothesis testing or to detect significant change in outcomes. In general, participant scores were mid-range of scale scores at baseline, indicating a floor or ceiling effect did not occur, and scores improved following the intervention. Action and coping planning, in particular, improved, consistent with the emphasis on setting specific goals, identifying potential obstacles to goals, and strategies for minimizing obstacles during

Table 4. Baseline scores and change scores for the behavioral determinants of change in the Pathways Diabetes Intervention.

Low GI food items[a]	Baseline value Mean (±SE)	Change score Mean (±SE)	Cohen's *d*[b]
Outcome expectancies (7 items)	4.2 (±0.1)	0.1 (±0.2)	0.15
Behavioral intention (8 items)	4.1 (±0.2)	0.3 (±0.2)	0.51
Action SE (9 items)[c]	6.5 (±0.6)	2.4 (±0.7)	1.45
Coping SE (4 items)	3.5 (±0.3)	0.7 (±0.4)	0.78
Recovery SE (4 items)	3.5 (±0.3)	0.9 (±0.4)	0.97
Action control (9 items)	3.5 (±0.3)	0.1 (±0.3)	0.09
Action planning (5 items)	3.3 (±0.3)	1.0 (±0.3)	1.40
Coping planning (5 items)	2.5 (±0.3)	1.4 (±0.3)	1.94
PA items[a]			
Outcome expectancies (16 items)	4.1 (±0.1)	0.2 (±0.1)	0.46
Behavioral intention (1 item)[d]	6.8 (±0.8)	1.5 (±1.0)	0.69
Action SE (13 items)	3.1 (±0.1)	0.1 (±0.1)	0.21
Coping SE (4 items)	3.7 (±0.2)	0.2 (±0.3)	0.27
Recovery SE (4 items)	3.8 (±0.2)	0.3 (±0.3)	0.46
Action control (5 items)	3.1 (±0.2)	0.4 (±0.2)	0.58
Action planning (4 items)	4.2 (±0.3)	1.4 (±0.3)	0.65
Coping planning (3 items)	2.9 (±0.3)	0.9 (±0.4)	0.87
Disease risk and self-regulation items			
Composite risk perception of diabetes and its complications (26 items)[e]	12.0 (±0.4)	-0.1 (±0.5)	-0.10
Hope State Scale: total score[f]	5.8 (±0.3)	0.8 (±0.2)	0.90
Pathways subscore (3 items)	6.4 (±0.3)	0.4 (±0.2)	0.46
Agency subscore (3 items)	5.2 (±0.5)	1.3 (±0.3)	1.04
Brief Self-Control Scale (10 items)[g]	3.5 (±0.2)	0.1 (±0.2)	0.14

[a]Response options ranged from 1 = 'strongly disagree' to 5 = 'strongly agree,' except where indicated, with higher scores being more favorable.
[b]Based on Cohen's *d* for effect size estimation.
[c]Response options ranged from 0 = 'strongly disagree' to 10 = 'strongly agree.'
[d]Response options ranged from 0 = '0%, not at all confident or likely' to 10 = '100%, extremely confident or likely.'
[e]Composite score across five subscales measuring personal control, worry, optimistic bias, personal disease risk, and comparative environmental risk with a 4-point response format; higher score indicates greater comparative perceived risk.
[f]Response options ranged from 1 = 'definitely false' to 8 'definitely true.'
[g]Response options ranged from 1 'very much like me' to 5 = 'not at all like me.'

intervention sessions. The magnitude of effect was moderate ($d = 0.50$) to large ($d = 0.80$) for intentions, action planning, and coping planning (Cohen, 1988). Of note, agentic thinking improved more than pathways thinking on the State Hope Scale; scores obtained from the brief Self-Control Scale also improved.

IM steps 5 and 6: full-scale program implementation and evaluation

Overall, the Pathways intervention was well accepted by pilot study participants based on session attendance, engagement during session activities, and feedback both during and following group sessions. IM provides a standardized method for intervention development and reporting, and the process facilitated grounding the Pathways intervention in self-regulation theories. Preliminary findings from the feasibility study showed that assessment questionnaires were appropriate and the intervention may facilitate improvement in self-regulation determinants of change.

More emphasis on pathways thinking, however, is needed during the intervention in future trials based on subscale change scores from the Hope State Scale. Three sessions (see Table 3) included the use of goal maps to specifically identify pathways to goal attainment, obstacles, and 'routes' around these obstacles. Participants were unfamiliar with the

goal mapping process and more time should be devoted to this practice during the intervention for greater skill-building; this modification will be incorporated into future versions of the Pathways intervention. In addition, study interventionists recommended introducing the concepts of self-talk (week 5) and values (week 9) earlier during the intervention and more consistently (not just 1 session) throughout the intervention. The intervention will be modified to introduce positive self-talk and core values earlier, move some of the GI information later, and return to value-driven decision-making consistently throughout the intervention. A more consistent focus on values also may improve self-control by emphasizing long-term goals over the immediate here-and-now.

Finally, some participants felt the PA goal of 150 minutes/week was too ambitious at baseline and they needed to initiate PA more slowly. While we discussed starting with 10 minutes of PA if that was necessary, some people needed reassurance that setting progressive goals was acceptable.

Discussion

This paper describes the development of a novel behavioral intervention that addresses key components of diabetes self-management, consuming a healthy diet and engaging in regular PA. The Pathways intervention was grounded in determinants of self-regulation and the HAPA theoretical framework. Using this framework, a person develops an intention to change a behavior and the intention is translated into action using a performance plan. Once an action has been initiated, however, it has to be maintained. Newly adopted behaviors are not achieved through a single act of will; they involve self-regulatory skills and strategies, which were incorporated into the Pathways intervention. Experience from the Pathways feasibility study supported the IM framework as a logical, comprehensive, theory-based approach to intervention development and evaluation. Findings from the feasibility study demonstrate that the Pathways intervention facilitated greater intention to make dietary and PA change and improvement in hope, planning, and SE, particularly SE for eating a lower GI diet. Future versions of the intervention should place greater emphasis on value-based decision-making, the goal mapping process, and gradual but progressive increase in PA for participants who are sedentary at study enrollment.

Planning and SE are targeted in HAPA to improve behavioral outcomes, and behavioral outcomes may improve clinical outcomes such as weight control and glycemia. Prior longitudinal survey research found that the HAPA framework explained fruit and vegetable intake and PA (Schwarzer et al., 2007). In these studies, planning and recovery SE were proximal predictors of behavior, and planning served as a mediator between intention and behavior. These initial studies provide support that planning and SE are key determinants of diet- and PA-related behaviors. While the current feasibility study was not designed to conduct mediation analyses, action and coping planning for both diet and PA increased substantially, consistent with the focus on planning in the Pathways intervention. In the Greater Green Triangle Diabetes Prevention Project, a HAPA-based intervention conducted through primary care clinics resulted in significant improvement in weight, blood glucose, and lipid levels, indicating a 23% reduction in T2DM risk (Laatikainen et al., 2007). Further research is needed to evaluate the impact of the Pathways intervention on these outcomes, which are key markers of optimal diabetes management.

The impact of the Pathways intervention on behavioral outcomes, such as diet and PA should be determined. Prior research among adults with T2DM following a low-intensity self-guided intervention based on HAPA found significant improvements in healthy eating for both the intervention and control groups (MacPhail, Mullan, Sharpe, MacCann, & Todd, 2014). Improvement in both treatment groups may represent a measurement effect whereby participants report behavior change simply by being asked (Morwitz & Fitzsimons, 2004). Thus, more interventions, such as the Pathways intervention, are needed in adults with T2DM to determine whether and how well interventions based on self-regulatory models facilitate the adoption and maintenance of health-related behaviors. The reported study is one step in this endeavor.

Given that this initial study was a feasibility study, the efficacy of the Pathways intervention was not a study goal. Pilot studies are recommended to evaluate the feasibility of study procedures and treatments provided and to assess acceptability (Lancaster, Dodd, & Williamson, 2004). Future research is needed to fully implement the intervention among a sample of adequate size to formally evaluate the impact of the intervention on theoretical determinants of change, consumption of low GI foods, and level of PA compared to an appropriate control condition. Multiple dietary recalls or food records are needed to fully evaluate the impact of the intervention on the target behavior of dietary GI and servings consumed. Accelerometry can be used to assess intervention impact on intensity and duration of PA, the second target behavior. The Pathways intervention primarily focused on individual determinants of change; however, social and environmental determinants also influence diet- and PA-related behaviors (McLeroy, Bibeau, Steckler, & Glanz, 1988). While the intervention was delivered in a group format to foster social support, a greater emphasis on developing social networks to support lifestyle change may be needed. A supermarket session was incorporated to help participants apply behavioral strategies during grocery shopping. However, we did not specifically target environmental determinants of change. While better addressing social and environmental determinants of change may improve intervention efficacy, a longer intervention duration and greater resources would likely be needed.

Conclusion

In summary, the Pathways intervention is well grounded in theories of self-regulation and potentially effective mechanisms of behavior change (Michie, Whittington, Abraham, McAteer, & Gupta, 2009). These mechanisms are described, consistent with calls for greater clarity regarding intervention development (Michie & Abraham, 2004). Based on current pilot testing, a larger randomized control trial that incorporates appropriate intervention modifications is warranted and this modified intervention has a greater probability for success.

Disclosure statement

No potential conflict of interest was reported by the authors.

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