Title: Development of a theory and evidence-based digital intervention tool for weight loss maintenance: the NoHoW Toolkit

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Abstract

Background: Many weight loss programs show short-term effectiveness, but subsequent weight loss maintenance is difficult to achieve. Digital technologies offer promising means to delivering behaviour change approaches at low cost and on a wide scale. The NoHoW project was a European Commission H2020-funded project aimed to develop, test, and evaluate a digital Toolkit designed to promote successful long-term weight management. The Toolkit was tested in an 18-month large-scale international 2 x 2 factorial (motivation and self-regulation versus emotion regulation) randomised controlled trial, conducted in overweight/obese adults who lost ≥5% of their body weight in the preceding twelve months before enrolment into the intervention.
Objective: This paper describes the development of the NoHoW Toolkit focusing on the logic models, content and specifications, and results from user testing.
Methods: The Toolkit was developed using a systematic approach including (1) development of the theory-based logic models, (2) selection of behaviour change techniques, (3) translation of these techniques into a digital web-based app (NoHoW Toolkit components), (4) technical development, (5) user evaluation and refinement of the Toolkit.
Results: The Toolkit included a set of web-based tools and inputs from digital tracking devices (smart scales and activity trackers), with modules targeting weight, physical activity, and dietary behaviours. The final Toolkit was comprised of 34 sessions, distributed through 15 modules, providing active content over a 4-month period. The motivation and self-regulation arm consisted of 8 modules (17 sessions), the emotion regulation arm was presented with 7 modules (17 sessions), and the combined arm received the full Toolkit (15 modules, 34 sessions). The sessions included a range of implementations, such as videos, testimonies, and questionnaires. Further, the Toolkit contained 5 specific data tiles for monitoring weight, steps, healthy eating, mood and sleep.
Conclusions: A systematic approach to the development of digital solutions based on theory, evidence, and user testing, may significantly contribute to the advancement of the science of behaviour change and improve current solutions for sustained weight management. Testing the Toolkit using a 2x2 design provided a unique opportunity to examine the effect of motivation and self-regulation and emotion regulation separately, as well as the effect of their interaction in weight loss maintenance.

Trial Registration: ISRCTN88405328

Keywords (3-10): mhealth; behaviour change techniques; weight management; motivation; self-regulation; emotion regulation; self-monitoring; user testing; logic models;

Introduction:

Behaviour change interventions for overweight and obesity that target dietary behaviours, physical activity and other weight management components show beneficial effects in reducing weight and improving health at least in the short term (e.g., [1–2], but the majority of individuals experience weight regain over subsequent months and years [3–4]. Thus, a key challenge for such interventions is to find sustainable and scalable methods for long-term weight loss maintenance (WLM) [5, 6]. The emergence and rapid growth of digital behaviour change interventions (i.e. sets of activities or products designed to change specified behavioural patterns through digital technology), is one response to the urgent need for scalability and sustainability and can help to better understand the complexity behind individuals' decisions and engagement in behaviours that affect their health and well-being, including sustained weight management [1, 7].

While research on digital behaviour change interventions' effectiveness is at an early stage, existing reviews have found small effects and between-study variability on outcomes and behaviours [8,9]. These interventions can be optimized by identifying which features contributed to their effectiveness through systematic theory and evidence-based processes of intervention development, implementation, testing and reporting (e.g. Medical Research Council [10]; TiDieR guidance [11]).

In the context of weight management, core features of effective interventions include techniques in line with self-regulation theories such as *goal-setting*, *self-monitoring* of weight and behaviour, feedback on behaviour and weight, and *plans* to cope with *risk factors* for weight regain and relapse prevention (e.g. problem solving) [12–15]. Autonomous motivation has also been associated with change in energy balance behaviours for obesity management [16]. As the number of digital interventions based on self-regulation and motivation approaches to sustained weight management are limited (e.g., [17]) it is important to test if these theoretical approaches produce sustained behavioural changes in the context of WLM. In addition, contextual-based emotion regulation strategies that promote compassion, acceptance, and mindfulness [18-20] may also impact on behavioural changes that promote WLM [21]. With these considerations in mind we developed a theory-based toolkit (TK), delivered as a portfolio of embedded digital tracking technologies (smart scale and activity trackers), mini-apps, and web resources accessible via computer, tablet and mobile phone, as part of the EU H2020 project "NoHoW: Evidence-based tools for weight loss maintenance".

The TK was used in the international NoHoW innovative 2x2 factorial, randomized, single-blind, controlled trial for WLM. All four arms of the intervention included self-weighing and self-monitoring of activity using commercial Wi-Fi scales and activity trackers. The active control arm included access to generic weight management content, and the three intervention arms consisted of *motivation and self-regulation* content; *emotion regulation* content; and *combined motivation* and *self-regulation + emotion*

regulation content (Figure 1) (detailed information about the NoHoW project and trial can be found elsewhere [22]).

This paper aims to describe the processes involved in the development of the NoHoW TK to an appropriate stage for evaluation in the NoHoW trial.

NoHoW Toolkit Development

The development of the NoHoW TK followed a systematic and iterative process incorporating both theory and evidence-based approaches, and user testing to refine usability. The development involved a multidisciplinary team of researchers in behavioural science, obesity and weight management, exercise and nutrition, software development, data analytics, biomathematics and user experience. It consisted of five steps: (1) development of theory-based logic models; (2) selection of the content, i.e. behaviour change techniques; (3) translation of these techniques into a coherent digital web-based app (NoHoW TK components); (4) technical development; and (5) user evaluation and refinement of the TK for subsequent evaluation in the context of a RCT. Table 1 presents an overview of the development tasks, which are described below.

Step one: Development of theory-based logic models

The selection of the psychological and behavioural factors to be targeted by the TK was based on existing literature on the most relevant theoretical frameworks in the context of physical activity, healthy eating and weight management (e.g., [2]). Available evidence from behavioural weight management interventions [17], showed some support for the effectiveness of interventions based on self-regulation theories (e.g., [13,14,23] and self-determination theory (e.g., [16]. There is also an increasing evidence showing the impact of emotions in weight management [24,28], and that contextual-behavioural approaches can contribute to psychological well-being and weight management through the development of skills aimed at reducing automaticity of maladaptive patterns of behaviour (e.g. mindfulness, acceptance and compassion towards internal negative states) [28-32].

The available evidence formed the basis for the NoHoW research hypotheses that WLM could be supported by strategies that promote (i) self-regulation (setting optimal goals and reviewing them, action and coping planning, action control) and motivation factors (promotion of autonomous motivation *vs* controlled motivation, intrinsic goals and flexible regulation to change behaviours and maintain weight loss), (ii) emotion regulation factors that may undermine self-management of energy balance related behaviours (reduce weight-related shame and self-criticism, reduce difficulties in emotion regulation, and increase psychological flexibility, mindfulness and compassion) and (iii) interactions between (i) and (ii).

The NoHoW logic models, presented in Figures 2-4, schematically represents the relationships between: (1) the primary and secondary outcomes, including behavioural outcomes; (2) the theoretical mediators that were hypothesized to explain the effect of the TK content on the primary and secondary outcomes; (3) the content of the TK; and (4) the hypothesized moderators of intervention effects. We developed three logic models, one for each of the intervention arms: *motivation* and *self-regulation* arm; *emotion regulation* arm; and the *combined* arm. This task was executed by the behavioural science team with feedback from the larger project consortium members and the external advisory board.

Step two: Selection of behaviour change techniques

The next developmental task was the identification and selection of the specific techniques that would form the content of the NoHoW TK. This selection was derived from the literature reviewed (step one) describing the behavioural, motivation and emotion regulation techniques hypothesized to impact on the theory-based mediators of weight loss maintenance as represented in the logic models. For example, *providing choice* is a core technique to foster *autonomy*. We conducted an additional scoping review to identify intervention techniques and modes of delivery used in digital behaviour change interventions for changing health behaviours in the context of long-term weight management (see https://osf.io/d2f8z/). To ensure standardization in the description of the NoHoW TK the selected techniques were reported using the identifiers and labels from reliable taxonomies (when available), such as the Behaviour Change Techniques Taxonomy (v1) (BCTTv1) (e.g. BCTT 1.2 Problem Solving) [33], or the classification of Motivation and Behaviour Change Techniques (MBCT) (e.g. MBCT 6: Providing Choice) [34]. No taxonomy is yet available for the emotion regulation techniques.

For the *motivation* and *self-regulation* version of the TK, twenty-nine intervention techniques were selected: eleven from the BCTTv1 mainly focusing on goals, planning and self-monitoring; and eighteen from the classification of MBCTs targeting autonomy, relatedness and competence (full list of techniques available at: https://osf.io/g4uey/). For the emotion regulation arm, twenty-five techniques were defined, based on contextual-behavioural science approaches, specifically, Compassion Focused Therapy, Mindfulness-based interventions and Acceptance and Commitment Therapy (full list of techniques available at: https://osf.io/d9ctr/)

Step three: Translation of the techniques into the NoHoW TK components

Initially, the research team created user cases involving *personas* based on recent research identifying individuals in WLM [35] (which varied in age, gender, weight history, digital literacy, and reasons for participating in a WLM intervention), and s*cenarios* (e.g. first visit, throughout the intervention, and during a relapse) to describe the target users and their potential experiences when using the TK. This exercise provided the starting point for specifying the functional requirements of the TK and identifying

how the techniques selected in step three would be implemented, and also facilitated the development of a common language between content and technology development partners. A guidance manual was created to aid the teams involved in the development of the modular content of the TK. The manual stipulated that the content of each module should identify: (1) specific behavioural goal(s); (2) theoretical construct(s) targeted; (3) techniques targeted; (4) rationale: link between the goal, theoretical construct and techniques; and (5) the mode of delivery of each technique (e.g. video, text) described in a way that would inform the software developers and designers on how to implement them. Scripts were developed for each implementation.

The implementations of the techniques into TK components is described below. When the user logged in to the TK, the main view (Figure 5) consisted of a tile-based dashboard, which was available for all TK users; a personal route-map, which was only available for intervention users; a diary section (list of comments or reflections an user could add at the end of each session); and a help section (information about the study, FAQs and instructions for navigating in the TK). The first two are next described in detail.

Tile-based dashboard

The dashboard tiles provided an at-a-glance view to the user's most recent data. The TK presented separate tiles on physical activity, sleep, and weight data retrieved from the Fitbit activity tracker (Charge 2) and the Fitbit smart Wi-Fi scale (Aria) (Fitbit™ San Francisco, CA, USA)). Users could visualize their data for one week and for one, three, and six months. For the *motivation* and *self-regulation arm* and for the *combined arm*, the tiles also presented the user's goals/action plans and coping plans related to physical activity and diet. These plans could be reviewed at any time in the tiles. In addition, there were two tiles for mood and diet, based on responses to one single question "How do you rate your mood, at the moment?" and "How satisfied are you with your diet, at the moment?", respectively (5-star response scales). The tiles highlighted if no recent data existed, thus prompting continuation of monitoring. By clicking on a tile, the user could view long-term graphical feedback in different times scales and make self-assessments related to the variable using a star rating (screenshot available at: https://osf.io/fprzy/).

Personal map

The personal map contained the modules of the TK, expressed in sessions (screenshot available at: https://osf.io/svwce/).The sessions available depended on the arm to which the user would be randomized. Because the full content for each arm of the TK was available from the first day of use, it was considered useful to have a map to guide the user through the optimal theory-informed order of the content. When a user clicked on a module, the sessions of a module were displayed (screenshot available at: https://osf.io/svwce/). There were regular sessions (around five minutes) and short

sessions (one minute each) and the user was prompted to access one specific activity during the week. The *motivation and self-regulation arm* presented seventeen regular sessions, organized in eight modules. The estimated duration of these sessions ranged from three to nineteen minutes. There were also four short sessions. The *emotion regulation arm* presented seventeen regular sessions plus two short ones distributed through seven modules. The estimated duration ranged from two to twenty-seven minutes. The *combined arm* presented all sessions from both arms distributed in seventeen weekly modules.

Weekly emails prompted the user to access the TK session suggested for that week. These emails also provided general information about WLM, such as physical activity recommendations.

Tables 2 and 3 describe the module's sessions for all trial arms. The techniques selected were implemented in the sessions using various types of activities, or implementations, briefly described here (Full details can be found at: https://osf.io/tfcmh/):

1. **Whiteboard animations** – 1-minute videos, using animation to provide educational content. The TK presented videos about self-monitoring, self-confidence, myths and facts, flexibility and body image, autonomous motivation, evolutionary perspective of eating, opposite messages, food functions, shame and self-criticism, obstacles to a healthier life, compassion, and mindfulness (example available at: https://osf.io/rqba9/; full content available at: https://licensing.leeds.ac.uk/product/nohow-content).
2. **Questionnaires** – interactive exercises to collect data from the user and provide immediate feedback (for example, a brief questionnaire concerning the reasons for personal ideal weight (*motivation and self-regulation arm*) or concerning compassionate attitudes (*emotion regulation arm*) (example available at: https://osf.io/wbvj5/).
3. **Testimonials** – short personal stories describing for example the difficulties, challenges and successes in a weight management process (example available at: https://osf.io/amju8/). Users could choose between a story of a male or female character.
4. **Downloadable audios** – audios containing mindfulness exercises, lasting for about five minutes. They were only available in the emotion regulation and the combined arms.

In addition, the TK presented two other features:

a. Extra support: triggered when individuals reached a threshold of weight regain > 3% above their target weight. This extra module stayed available until users returned to a weight interval of ±3% (i.e. the interval defined as weight maintenance). For users in the *motivation* and *self-regulation arm*, and the *emotion regulation* arm, this support further directed the user to content useful for coping with relapses (see screenshot at: https://osf.io/epzxm/).

b. Individualized feedback: The *motivation and self-regulation* arm included an individualized feedback feature in which time series of data retrieved over 1-2 months for each participant (activity and sleep pattern from Fitbit devices, daily/weekly body weight measures taken by the Fitbit Aria Wi-Fi- scales and usage of the TK) were analysed to examine weight change patterns. There were also indicators of weekly vs weekend and earlier vs later in the week used as possible predictors to alert participants to weekly cycles in weight change. Feedback could only be provided if sufficient data was collected (at least thirty days, and variation in weight), and consisted of short messages such as "For you, being active or exercising seems linked to better weight management" or "Your weight management seems better on weekdays" that were displayed on the frontpage of the homepage.

Step four: TK technical development

We identified that the two most important functionalities of the TK were: (1) providing the WLM intervention in three theoretically informed, evidence-based versions and one control version (see above); and (2) supporting the digital tracking of weight, physical activity, and sleep. Given that the TK was intended to be used for several months, a positive user interaction and an attractive user interface (UI) were considered necessary. A user experience designer was involved in the iterative development of the most crucial UI elements. The design process started with scenario development and identification of the user requirements for the TK based on the scenarios, informing the development of initial UI concepts. The concepts were visualized by the user experience designer and tested in small-scale interviews with participants similar to the target users. The UI for the intervention sessions was designed through collaboration between the behaviour change team and the intervention designers. An Admin UI was developed to serve the needs of the intervention designers and trial managers. The intervention designers needed to be able to add, refine and update the content continuously during the TK development as well as to define the content, rules and schedules for different email prompts and reminders to be sent to TK users. The trial managers needed to create new users of the TK, assign them to different intervention arms, and manage their status depending on whether they were still involved in the study or not.

Figure 6 depicts the final overall architecture of the NoHoW TK and its connections to other systems required to deliver the intervention. The TK consisted of two layers. The front end consisted of an HTML skeleton with JavaScript modules. A responsive web design approach and mobile first concept was used in the development. The back end responds to front end requests, communicates with the MySQL database on the datahub server, and accesses Fitbit data on Fitbit's server. The datahub stores and analyses data, providing personalized feedback to users, relaying information back to users via the personalized feedback panels on the dashboard of the TK. The intervention content was delivered via text, images, videos, questionnaires, and interactive exercises. The text and images were implemented

as HTML. The videos were hosted on Vimeo (New York City, NY, USA) and embedded in the intervention sessions. The embedded questionnaires were implemented with Qualtrics (Qualtrics, Provo, UT and Seattle, WA, USA), which was also used for managing the study questionnaires in the RCT. New interfaces were built to retrieve questionnaire answers from Qualtrics and visualize them in the TK front end to enable exercises where instant feedback was needed. Interactive exercises were tailor-made as mini-apps. One example of a mini-app was an exercise enabling the users to visualize key moments in their personal weight management history as a graph.

Each user was provided with a user account to the TK website as well as a Fitbit account to gather activity, sleep and weight data. The personal map was designed iteratively with the help of a user experience designer. First, three different concepts for visualizing the personal map were designed and paper prototypes illustrating the concepts in different stages of use were created. The prototypes were evaluated with six participants in two evaluation rounds, first with three participants, after which major usability issues were fixed, and then, the updated prototypes were evaluated with another three participants. The evaluation consisted of 45-minute face-to-face sessions with each participant, who were asked to complete different tasks with the prototypes and provide feedback on the usability and visual appearance of the concepts. Finally, the participants were asked to rate the concepts as the best, second best, and worst. A concept illustrating a path on a map received the highest ratings and was selected. The final design was created by incorporating user feedback and some highly-rated features from the other two concepts. All intervention modules were displayed on the main level of the map, and completed modules were highlighted in pink while modules that have not been completed yet were highlighted in a lighter shade of pink. When a user clicked on a module, the sessions of that module were displayed. This level of the map also indicated which of the sessions had been completed. By clicking on a session, the user gained access to the intervention content. On both levels of the map, there was also a box at bottom left of the screen, indicating the next recommended session and providing a shortcut to the session.

The Admin UI served intervention developers and trial managers. The most important component in terms of the intervention was the content management system (CMS) due to the large volume of intervention content and the need to constantly refine and update it during the iterative development of the TK. Thus, enabling the intervention designers themselves to manage the content facilitated the collaboration between software developers and intervention designers. The CMS enabled the intervention designers to describe the intervention structure, content items and their relations to each other with a web-based user interface without programming expertise. The CMS is based on the Django CMS (www.django-cms.org/en/), but its functionality has been tailored to meet the needs of the intervention design.

Step five: User evaluation and TK refinement

We conducted two user evaluation studies. The first aimed to identify key technical and user experience-related issues and results from this study informed refinements to the NoHoW TK v1.0. This study was conducted in the UK with English-speaking adults, recruited primarily by advertisement or invitation from the University of Derby. Inclusion criteria were: aged ≥18 years, able to travel to the University of Derby, able to follow written and verbal information in English, ability to access the internet, currently or have been overweight in the past, with at least one weight loss attempt. Approval was obtained from the research ethics committee of the University of Derby. A mixed methods approach was used for the analysis of the data, through questionnaires, interviews, TK usage log data, and data from wireless scales and activity trackers (Fitbit™) (study description available at: https://osf.io/ezfv9/).

Thirty-seven eligible participants expressed interest in participating in the study, twenty participants started using the TK, fourteen of them completed the 5-day questionnaire and nine completed the 30-day questionnaire. The average age of the participants was forty-one years (range 23-63). Although retention was low, the collected data was sufficient to allow for the analysis for the feasibility study. Results from the study were used to revise the TK specifications. There were several improvements made to the TK regarding user experience design, content development, technical performance and usability (see detailed list of design implications in https://osf.io/ezfv9/). For example, to facilitate navigation in the TK, the personal map component was included; videos were re-filmed to make them more energetic and less clinical; and technical performance and usability were improved by ensuring scaling of the TK to different screen sizes and ensuring compatibility with different browsers and mobile platforms.

After refinement of the TK v1.0 into v2.0 and translation from English into Portuguese and Danish (languages of the three countries where the NoHoW trial was conducted), we conducted a second usability testing study with the Portuguese sample. This was a qualitative study consisting of in-depth interviews, with the aim of understanding users' motivation to engage with the TK, and which functionalities of the TK could promote user engagement (see https://osf.io/rhj5t/ for full description). In these interviews, conducted after changes were implemented on top of TK v1.0, participants were shown a beta version of the TK which included a demonstration of the navigation procedures, and one session of the TK. Interviews lasted approximately 1 hour, where audio recorded and transcribed verbatim. Thematic analysis was conducted using MAXQDAv12. Approval was obtained from the research ethics committee of the University of Lisbon.

Sample size was twelve adults (23-57 years) who lost between 10 and 43% of their weight prior to taking part in the qualitative study. Most participants had experience in using digital tools, mainly to

monitor their diet and physical activity. When testing the TK, participants did not report difficulties, and the fact that the TK could be used in both a computer and mobile phone was considered an advantage. Participants considered that the self-monitoring tools were positive elements and considered that engaging in 5-10 minutes sessions per week was a reasonable time commitment. From the interviews, it was concluded that all participants felt the TK content was acceptable, in particular the whiteboard videos were considered to be very appealing and engaging in terms of both the design and content (see https://osf.io/rhj5t/ for full results).

Final NoHoW Toolkit

The final version of the NoHoW digital TK was presented in four versions available for each of the trial arms as well as three languages for each of the trial centres. As described in step three, all versions included a tile-based dashboard displaying data from digital tracking devices (Fitbit™ Charge 2 wrist device, and Aria smart scales) for weight, steps, and sleep, and manually entered data for eating and mood. It also included a diary section and a help section. In addition, the three versions available to each of the intervention arms –*motivation and self-regulation, emotion regulation* and *combined arm*, displayed a personal map containing the modules of the TK. The final TK was comprised of thirty-four sessions, distributed by fifteen modules, with active content being presented for four months. The motivation arm consisted of seventeen sessions, distributed in eight modules; the emotion regulation arm was presented with seventeen sessions distributed in seven modules; and the combined arm received the full TK.

Challenges and Lessons learned

Using explicit theory when developing interventions allows for the identification of what factors influence the target behaviour, the mechanisms of action(s) that operate along the pathway to change, the best techniques to influence these factors, and how these can impact on engagement. One challenge we faced in the development of the NoHoW TK was the integration of the motivational and self-regulation theoretical approaches with emotion regulation, to be tested in the 2x2 factorial trial. Because there was no theory or empirical support for the interactions between these approaches, the combined arm provided access to all the TK content available, and users were prompted each week to access both the emotional and the motivational and self-regulation content. Further, there was some overlap between the sessions from the different approaches, e.g. session on values, and on flexible eating.

While we used up-to-date frameworks to guide our choices for the content, structure and flow of the TK, final decisions on which components/features to include and how these would be implemented also drew on the research team's judgement through iterative discussions, informed by user testing and

feedback. Unfortunately, the decisions made in the development process werw not systemically justified and documented. Current frameworks and guidance provide little information on how to translate behaviour change techniques into digital content (features), for example what is the best way to implement a modelling technique in a digital intervention to be most effective, using e.g. a video, text, audio or combinations? Behaviour change techniques do not influence only the intervention content, but also the functionality of that content - how users interact with and use the app. This in turn affects how behaviour change techniques can be translated into individual functionalities and how these functionalities form an overall concept that creates value for the user. Efforts are currently in place to develop tools to support researchers and interventionists in standardizing reporting to inform intervention design, content and delivery (e.g., [36,37]).

The development of the NoHoW TK involved close collaboration between behavioural scientists and the web developers. The TK (and hence intervention) design was developed at the beginning of the project and limited by time and resources. Development was accelerated by, where possible, using existing commercial solutions such as implementing intervention exercises using Qualtrics questionnaires, and using commercially available tracking devices and their data aggregation capabilities. The resource constraints meant negotiating acceptable compromises between the teams in the implementation of some TK components. It was difficult to evaluate beforehand how much work each functionality required and how essential it actually was considering the evidence base.

It can be challenging to develop a totally new digital behaviour change intervention in a time-limited project that includes a large-scale effectiveness evaluation. The schedule for the development was tight, which causes pressure to use existing commercial platforms in the development. Although including commercial options such as Fitbit can be an advantage as we can test real world solutions, it also means less control over the features that are regularly added to the Fitbit app and trackers, which can contradict or be in conflict, or overlap with the content provided in the NoHoW TK, e.g. the built-in “breathe” exercise in the Fitbit was not aligned with the relaxation techniques recommended in the TK. Future interventions may favourably control these features by using devices used for research or co-developing these with commercial partners, for example, by integrating new features on the FitBit native app that would be released to the NoHoW participants only. Further, developing a web-app instead of a native mobile app limited the functionality and interaction mechanisms from the intervention design point of view. Focusing on the web-based app saved the trouble of developing separate applications for multiple platforms (Android, iOS) and related CMS enabled updating the intervention content in real-time.

While a factorial RCT allows a rigorous testing and comparison of different theory-based components, it also presents constraints to the continuous optimization of content to the individual that

may arise during the trial (i.e. the content could not be updated during the full length of the NoHoW trial). The use of optimization designs for digital interventions (e.g. SMART [38] or MRT [39] approaches) can support the identification and delivery of content of interventions through the modelling of causal and time-varying effects, providing a more personalized and dynamic approach to complex behaviour change in the context of long-term weight management.

Considering these challenges, it is likely that the interaction between academia and industry will be crucial to the development of digital behaviour change solutions in the years to come. Industry has technical capabilities and capacity that could potentially synergise with academic efforts in developing rigorous, systematic and dynamic behaviour change interventions, grounded on sound theoretical principles.

Conclusion

The NoHoW TK is a theory-based web-app aimed at supporting individuals who have already lost weight and are trying to manage their weight in the long term. It was systematically developed using standardized guidance, an interdisciplinary approach, design principles and user testing, and formally evaluated through a 2 x 2 factorial randomized controlled trial. It presents modular content on motivational factors of behaviour change, behavioural regulation skills, and emotional regulation, and integrates data from activity trackers and weight scales. The development of the TK involved a multidisciplinary and international team of experts who used a systematic and rigorous approach to derive at its technical specifications and content limitations. The TK has been tested in the context of a multi-country randomized trial, and in addition to the main trial results, also results from the mediation-moderation analysis, guided by the logic models will further inform about the most effective and engaging components for WLM, therefore contributing to the optimization of the NoHoW TK in future deployments.

Contributors: RJS, BLH, PJT, FFS, ME and GH conceived the NoHoW project. MMM, ALP, PJT, EM, PV, MM, CD, GH, ME and JL designed the toolkit. All authors contributed to the development of the content and functionalities of the toolkit. MH, EM, RJS designed the user evaluation in the UK. MMM, ALP, JE conducted the Portuguese usability study. MMM, ALP, JE, EM, MH, CD and MM drafted the manuscript. All authors reviewed and approved the manuscript.

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Figure 1. The NoHoW trial Design, 2x2 RCT

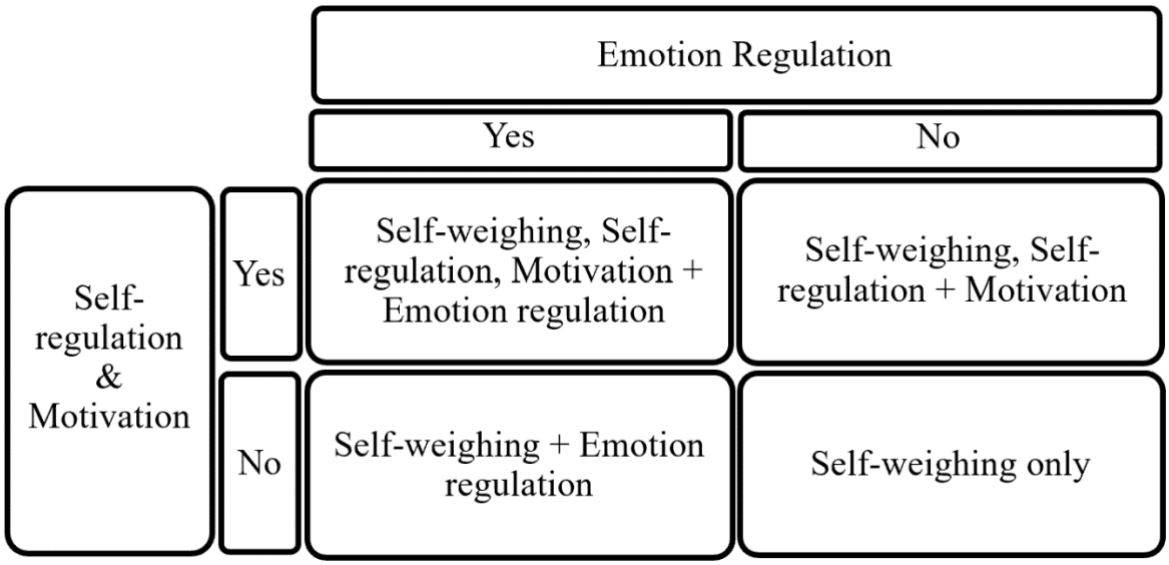

Table 1. NoHoW Toolkit development process

Tasks	Team responsible
1. Persona and scenario development	Behavior change team & UX team
2. Development of the overall content of the toolkit (e.g. sessions), based on the motivation, self-regulation and emotion regulation theories of behavior change	Behavior change team
3. System architecture design	Software development team
4. Full description of each implementation (technique or clusters of techniques) for each content feature (e.g. session)	Behavior change team
5. Development of a list of possible modalities in which the techniques would be implemented, e.g. quiz, animation video, audio, text, testimonial	Behavior change team
6. Feedback about feasibility of to implement, engaging, other options and details on the technical implementation	Software development team
7. Adjustments in accordance	Behavior change team
8. UI design	UX team & Software development team
9. Functional description	Software development team
10. Programming	Software development team
11. Feasibility study plan	UX team
12. Toolkit sessions upload using a content management system	Behavior change team
13. The implementation is user-tested	Behavior change team & Software development team
14. Final adjustments	Behavior change team & Software development team

Figure 2. Logic Model Motivation and Self-regulation Arm

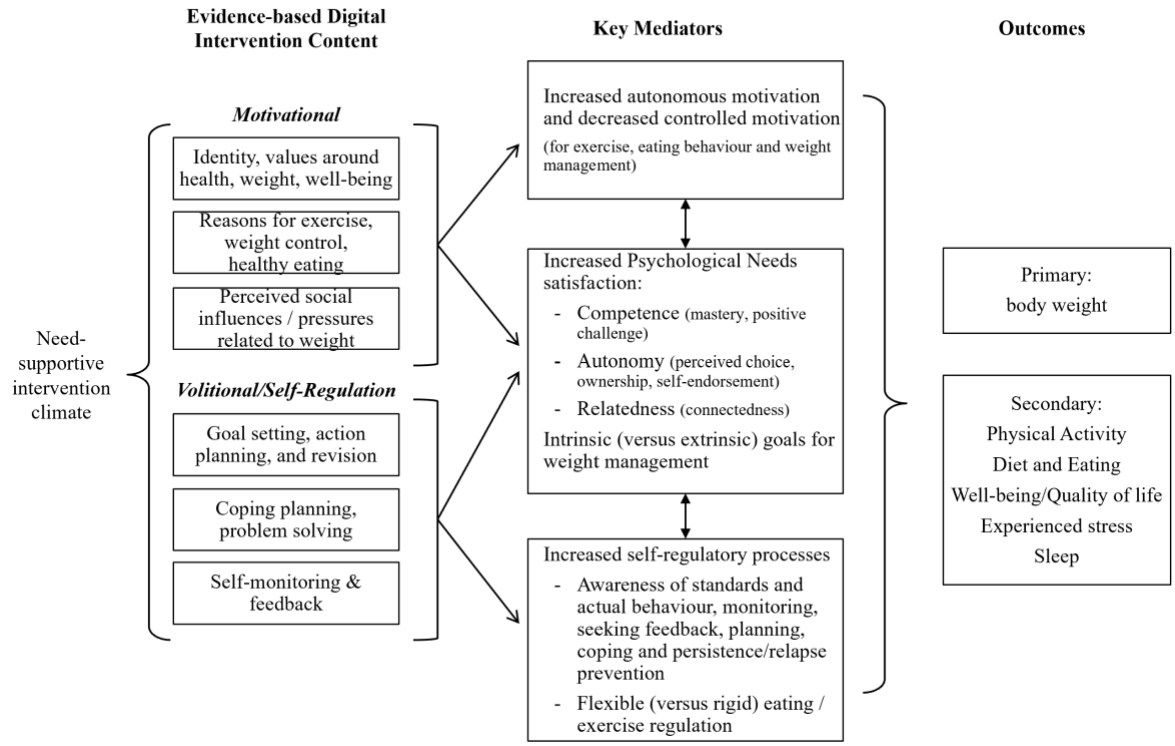

Figure 3. Logic Model Emotion Regulation Arm

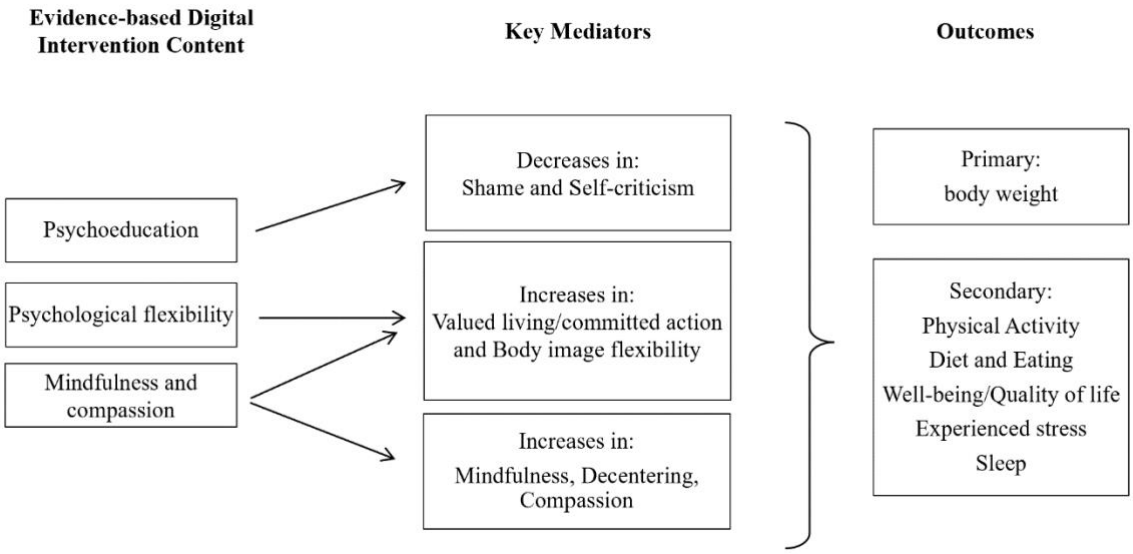

Figure 4. Logic Model Combined Arm

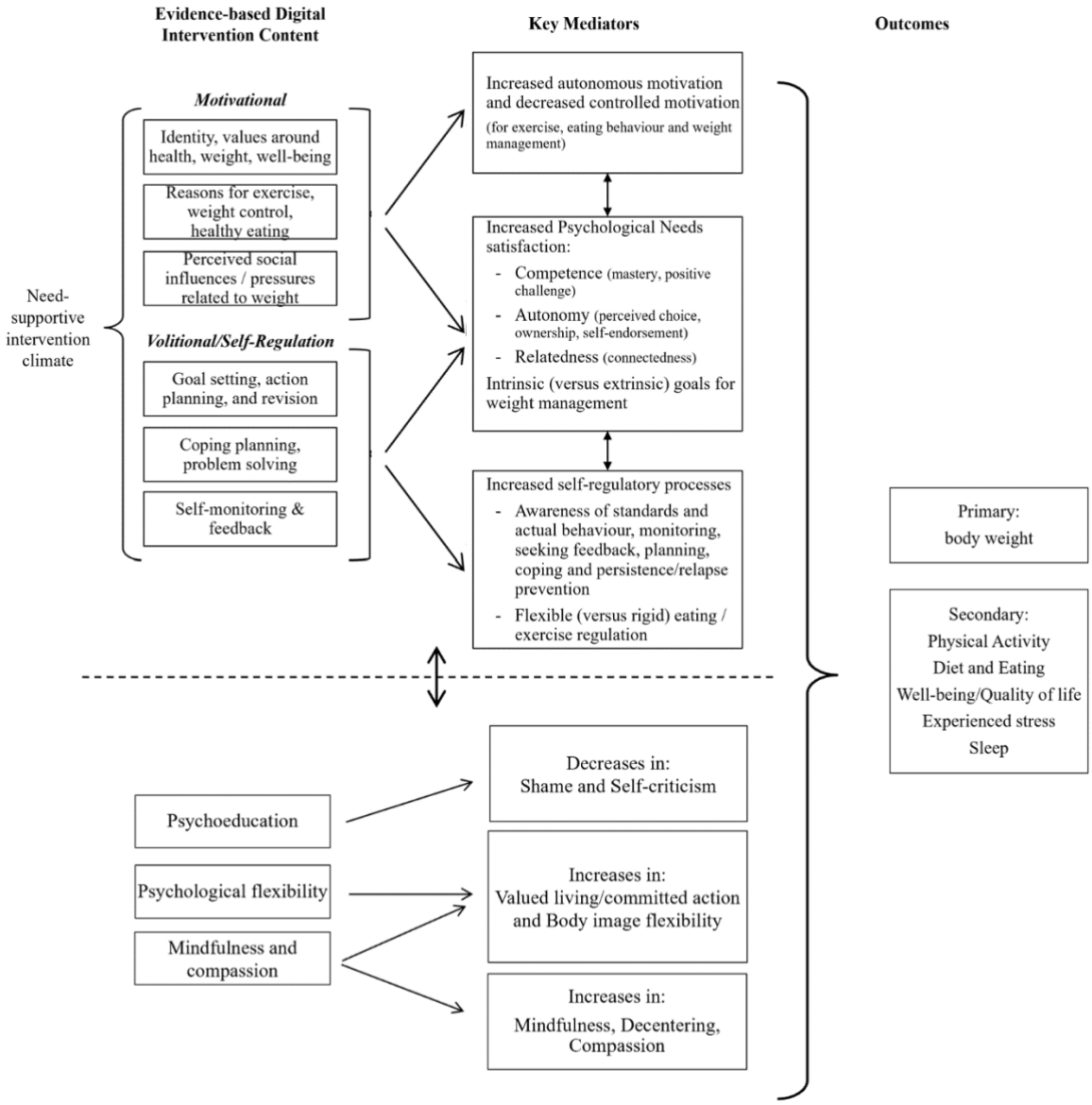

Table 2. Theme and Goals of each module of the Motivation and Self-regulation Arm

Module (Theme)	*Core goals*	*Mediators*
1. My weight history	1) Review weight change history: weight trajectory, characteristics of previous weight changes (strategies and feelings associated). 2) Identify weight loss strategies/ approaches used in the last WL attempt and assess their sustainability in time.	Self-awareness Competence
2. My Weight Goal	1) Learn about self-monitoring and self-referenced feedback, its role on with goal setting/revision, and reflect on individual options and preferences 2) Reflect on ideal and acceptable weights (and where those originated/ mean to the person). 3) Understand the importance of setting self-relevant and optimal goals: Set weight-related goal	Self-regulation capacity Competence Autonomy (ownership) Intrinsic (vs. Extrinsic) goals
3. Myths and facts	1) Promote factual knowledge about energy balance-related behaviors (exercise and diet) and WLM.	Competence Autonomous motivation
4. My healthy goals	1) Promote awareness of multiple choices around behavior changes and WLM at the long-term (there is no "right" way). 2) Finding individual interests and seeking enjoyment and personal meaning around health behaviors. 3) Explore personal resources for engaging in health behaviors (e.g. skills).	Autonomy (perceived choice); Autonomous motivation; Competence Self-regulation capacity
5. My goals and values	Prompt reflection on personal reasons for WLM (weight goals) and related-behaviors, by differentiating internal (autonomous) and external (controlled) motives, and its relation with sustained behavior change (sense of ownership). Explore sources of body image/ideal (e.g. societal norms, media, significant others), and its consequences (motivation, well-being). 3) Prompt reflection on how WLM and related-behaviors goals (and what has already been achieved) can be linked to deeper values and beliefs.	Intrinsic (vs. extrinsic) goals - life aspirations Autonomous vs controlled motivation Autonomy (ownership) Perceived social influences/ pressures related to weight
6. Free and Flexible	1.Identify functional and dysfunctional investment in body appearance (by exploring sources of body image/ideal (e.g. societal norms, media, significant others), and its consequences (motivation, well-being) and promote satisfaction with one's body, at any size. 2.Explore links between internal (feels free and choiceful) and external (feels pressured) motives and eating and exercise regulation (e.g. rigid vs. flexible approach).	Intrinsic (vs. extrinsic) goals Autonomous vs. controlled motivation Autonomy (ownership) Rigid vs. Flexible behavior regulation
7. What gets in the way…	1) Identify challenges/barriers to current behavioral patterns, and identify resources to increase capability to deal with them. 2) Identify strategies to deal with these barriers (coping plans) and to focus attention on how behavior changes serve other important life goals	Competence Autonomous motivation Self-regulation capacity
8. My support system	1) Identify sources of social support and reflect on what they mean (e.g., pressured, conditional support vs. unconditional). 2) Increase skills in seeking social support and dealing with social / peer pressures (e.g. assertiveness). 3) Explore reaching out to others as a role model or source of support and expertise in WLM.	Relatedness Autonomous motivation Perceived social influences / pressures related to weight Self-regulation processes

Table 3. Theme and Goals of each module of the Emotion Regulation Arm

Module (Theme)	Core goals	Mediators
1. Why do we eat?	Promote the understanding of the difficulties in regulating eating behaviour because our systems are not yet evolved to restrict eating behaviour. It's not our fault. Promote the knowledge about how our body works, to stop people from fighting against their bodies but working with them instead. Promote the understanding that food has multiple functions. It's not our fault. Promote the reflexion about the conflicting messages in our modern society about eating and physical activity, and using food as a way of comfort and achieving a thin and fit body image. Clarify how these conflicting messages create additional stress and how eating may emerge as away to soothe the self and manage stress.	Evolutionary approaches to eating behaviour and physical activity; De-shaming; Emotion regulation
2. Eating Awareness	Unveiling emotional and stress eating. Identify he traps in using food to regulate emotions and cope with stress. Learn how to eat mindfully. Promote awareness of satiety and hunger cues	Emotional eating Emotional regulation Mindfulness
3. Roadblocks to change	Do we need shame and self-criticism to manage our weight?: Understand the evolved functions of shame and self-criticism Clarify the negative effects of self-criticism and shame on weight management , body image, and physical activity Consolidate the inefficacy of shame and self-criticism to cope with stress and maintain changes Promote creative hopelessness	Shame; Self-criticism; Creative hopelessness; Stress management
4. Living a healthy life	Foster creative hopelessness Promote the clarification of values Identify how life can be so disconnected from values Identify the obstacles to a valued life Discuss the role of avoidance and the control agenda as obstacles to valued life Create value related goals and step-by-step actions Encourage committed actions to values in daily life: The importance of healthy eating patterns and physical activity	Creative hopelessness; Values; Avoidance; Control agenda; Committed action;
5. Learning to just be	Introduce and reduce automatic pilot Reflect on the needed shift from the doing mode to the being mode Clarify what is mindfulness and evidence of its benefits Increase awareness and acceptance of the present moment Using the breath as an anchor for the present moment Introduce the 3-Minute breathing space as a way of being fully present with a different frame of mind Learn how to use the 3-Minute breathing space to deal with difficult emotions, sensations, thoughts or the stress of daily life Learn how to use the body as an anchor to the present moment experience Increase awareness and acceptance of unwanted internal experiences (emotions and physical sensations) Increase awareness of the body and the body in movement Use mindfulness to take better care of your body	Mindfulness; Automatic pilot; Being mode; Acceptance; Awareness; Coping; Bodily awareness; Mindful movement; Decentring; Emotional regulation.

	Increase awareness and acceptance of thoughts Promote a defused perspective on thoughts: Thoughts are not facts Promote an observer perspective of internal experiences Promote the identification and awareness of stress responses in the body Foster a more adaptive and healthy way to cope with stress and negative emotions	
6. Cultivating compassion	Introduce Loving-kindness Understand how the need for compassion emerges from our evolved brain and emotional systems Understand what is compassion Clarify that compassion takes courage Learn to the basic skills to cultivate compassion Learn how to prepare the body for the compassion practices Develop and cultivate the qualities of the compassionate self Understanding the role of interpersonal difficulties and how stigma generates stress Cultivate compassion in my relationship to others Identify the main reasons people report to fear compassion Clarify what compassion is and is not Discuss the paradoxical effects of fears of compassion Help people to overcome their fears of compassion Cultivate self-compassion (of one's body image, thoughts, emotions) Building the capacity for acting compassionately towards one's body Taking the courage to engage in hard but necessary actions: The importance of physical activity	Compassion; Loving-kindness; Postures; Facial expressions and voice tones; Soothing rhythm breathing; Compassionate imagery; Compassion for others; Fears of compassion; Self-compassion;
7. Final destination: A new start	Promote the early identification of relapse signals Distinguish lapse from relapse Draw an action plan to deal with relapse Prevent new relapses	Relapse prevention; Mindfulness; Committed action.

Figure 5. NoHoW Toolkit Dashboard

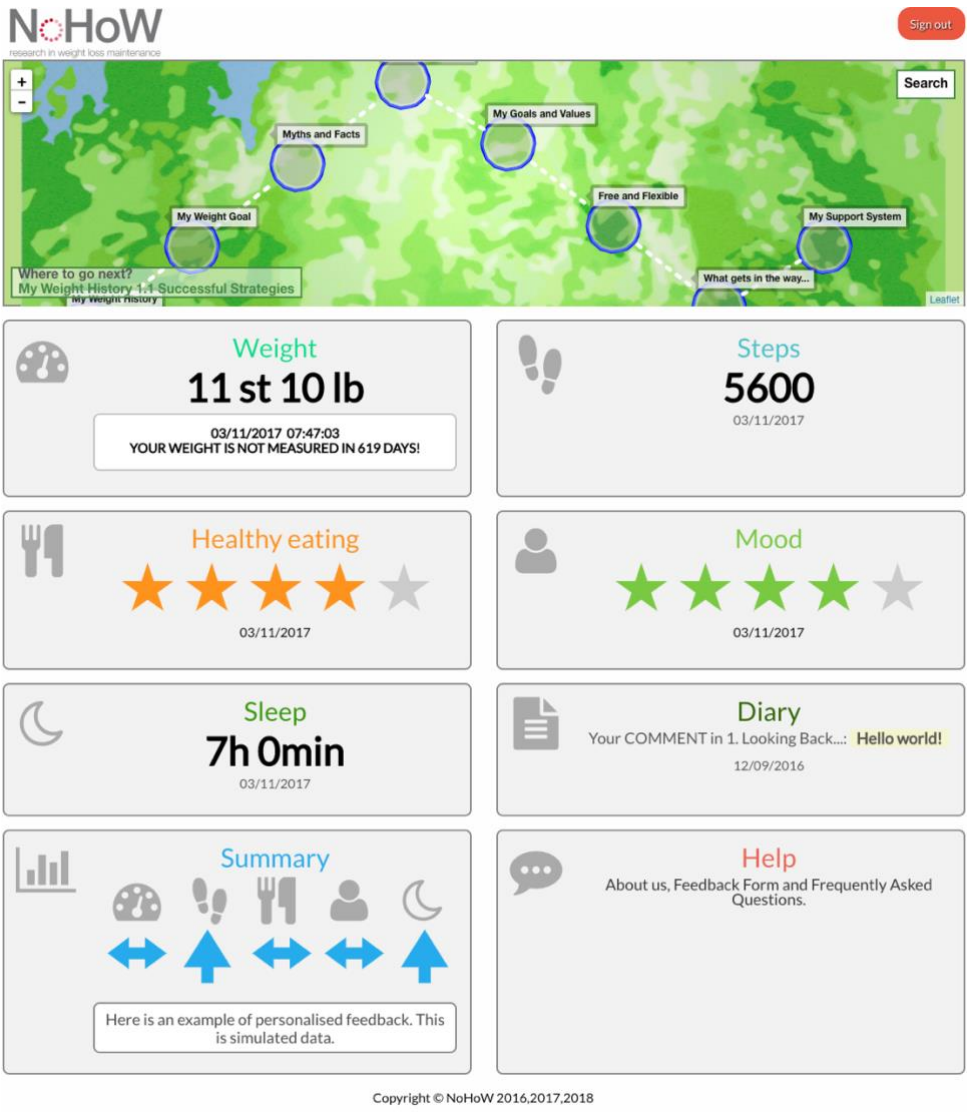

Figure 6. The overall architecture of the NoHoW Toolkit and its connections to third-party systems.