Overweight, obesity and associated diseases are major societal challenges for the health of European citizens. Most individuals can manage to lose weight, but few manage to maintain their weight loss in the long term. The key challenge in managing obesity in Europe and beyond is therefore not weight loss per se, but weight loss maintenance. The overall aim of the NoHoW project is to develop a kit of IT-based tools (NoHoW Toolkit (TK)), based on a robust evidence foundation about long-term weight management and the most promising behavioural science techniques for weight loss maintenance (WLM). Once developed, we will investigate the effectiveness of the TK to support long-term behaviour change related to weight loss maintenance through a randomised controlled trial (RCT) in the UK (University of Leeds (UNIVLEEDS)), Denmark (RegionH (RH)) and Portugal (University of Lisbon (FMH)). The results of the project will directly feed into the development of new products and services, providing much needed WLM services that promote health education and long-term weight management, thereby contributing significantly to solutions to the obesity epidemic.

Overview from the Coordinator (WP8)

This report summarises progress in the first two years of the project, including:

- a population-based survey in the UK, Denmark and Portugal to examine the socio-demographic and psychological predictors, experiences, practices and support needs for weight management,
- a series of qualitative interviews with individuals who successfully lost weight and are seeking to maintain their weight loss to investigate how individuals self-regulate food intake and the impact of emotional states and stress on those practices,
- a systematic review of behaviour change theories and techniques used in previous IT-based interventions aimed at improving physical activity, diet and weight control,
- development and feasibility testing of the NoHoW TK v1.0, leading to refinements and implementation of v2.0 in English, Danish and Portuguese,
- development and implementation of an IT infrastructure and central data storage facility for all RCT data (data hub), including data exchange mechanisms between all data sources and the data hub,
- development of prediction models for individualised feedback to participants in the trial,
- development and ethical approval of the NoHoW trial protocol and associated documents,
- completion of a pilot of the NoHoW trial in the UK, Denmark and Portugal,
- conduct of an Exploitation Workshop, including initial stakeholder mapping, and
- development of a ‘corporate’ brand for the project and engagement with key stakeholders (including explainer video, press releases, media coverage, social media, patient councils and e-newsletters).
WP1 - Evidence Foundation

AIMS

WP1 is building a solid evidence foundation for the: (1) development of the NoHoW TK, (2) conduct of the NoHoW trial, and (3) interpretation of the results of the NoHoW trial. Specifically, WP1 aims to understand the demographic, socio-economic, seasonal and psychological predictors, experiences, practices and support needs for WLM amongst Europeans, as well as understand the role of self-management of stress and emotions alongside self-management of energy balance behaviours in WLM. We also seek to identify predictors of successful WLM in successful weight maintainers.

ACHIEVEMENTS

Significant progress has been made in establishing a rigorous evidence-base of how weight is lost and maintained in Europe as a foundation for the NoHoW project and to address the general lack of knowledge about long-term management of weight loss. We have developed, delivered and analysed the results of a bespoke online survey to examine socio-demographic and psychological predictors, experiences, practices and support needs for weight management in representative adult samples in the UK, Denmark and Portugal with the successful recruitment of a total of 2,000 respondents. The survey revealed that many respondents had a long history of multiple prior weight loss attempts. 66% of the total respondents reported a clinically significant weight loss of 5% or more, and 26% of the sample maintained a weight loss of 5% or more. Interestingly, most weight loss attempts were undertaken without any formal support. Most respondents did not engage with or understand evidence-based behaviour change strategies associated with successful weight management. For example, self-weighing was infrequent, particularly in the UK. Misinformation about what constitutes effective weight loss methods was also widespread. Preliminary results from the survey were presented at the European Health Psychology Society and British Psychological Society Division of Health Psychology Conference (Scotland, Aug 2016), and a full manuscript is currently in preparation.

In addition, we have completed qualitative interviews with 56 people in the UK, Denmark and Portugal to examine in-depth self-regulation of intake, emotions and stress in order to identify WLM support needs. We found that interviewees used multiple self-regulatory strategies to control food intake through the process of acquiring, preparing and consuming food. We also found that the emotion-regulation activities of interviewees varied widely. Dysregulated eating during times of stress was a common theme and interviewees highlighted a need for accessible support when they were at greatest risk of weight relapse. A number of manuscripts are planned to describe the full results.

During the feasibility study of NoHoW TK v1.0, qualitative interviews were also undertaken to investigate user impressions (appeal, interest, motivation) of the TK to inform the final version to be used in the NoHoW trial. Overall impressions of the TK were positive, in particular the use of videos and testimonials, and points for improvement were identified.

ON-GOING WORK

In Spring/Summer 2017, we will complete a second wave of the online survey in an independent sample in the UK, Portugal and Denmark to investigate seasonal effects in the timing and success of previous weight loss attempts. Furthermore, we are currently carrying out a longitudinal survey to identify predictors of successful WLM in successful weight maintainers, recruited from the membership of partner SlimmingWorld™ (SW). In Oct 2016, a total of 2,776 SW members were recruited to the study and completed baseline questionnaires with at least 80% data. Further questionnaires will be completed at 6 and 12 months.

TEAM

WP1 is led by Prof. Falko Sniehotta and Dr. Elizabeth Evans at the University of Newcastle (UNEW), with active participation by the teams of Prof. Liisa Lähteenmäki (University of Aarhus, AU), Prof. Pedro Teixeira, Dr. Marta Marques and Dr. António Palmeira (FMH), Prof. James Stubbs (UNIVLEEDS), Dr. Paul Sacher (SW) and Mr. Euan Woodward (European Association for the Study of Obesity, EASO).
WP2 - NoHoW Toolkit

AIMS

WP2 is dedicated to developing and implementing the NoHoW TK, which includes:

- conducting a systematic review of the literature, focusing on the theories and behaviour change techniques used in ICT-based interventions for weight management, diet or physical activity,
- translating evidence from the literature and gathered in WP1 to develop logic models, ICT implementations of behaviour change techniques and the TK specifications to support these implementations,
- developing evidence-based content and the technological platform to deliver the TK design and content (TK v1.0 in English),
- conducting a feasibility study of TK v1.0 in the UK to assess user experience and technical maturity, and
- delivering TK v2.0 in English, Portuguese and Danish for assessment in the NoHoW trial (WP4).

ACHIEVEMENTS

A systematic review of the behaviour change theories and techniques used in previous IT-based interventions aimed at improving physical activity, diet and weight control was conducted to inform the TK specifications. We found that only about half of the trials included in the review adopted a theoretical framework for intervention development. Those interventions that were theory-based supported the use of self-monitoring with self-regulation models, as planned in NoHoW. Interventions incorporating emotion regulation and stress management were scarce, but this was expected as this is an innovative aspect of NoHoW. The review also identified gaps in the evidence base (lack of theoretical selection of digital technologies, paucity of theory-based behaviour change techniques) that NoHoW will address.

Based on evidence from the literature, our systematic review and findings from WP1, FMH, University of Coimbra (UDC) and VTT Technical Research Centre of Finland (VTT) developed the specifications for TK v1.0. The specifications identified the required theoretical content and functionalities required for the TK. Logic models for each intervention arm were created, respecting the theoretical background and the ICT context specificities. The team created ICT implementations for each one of the logic models’ components. It was an iterative process, with several versions of the implementations to respect the theoretical tenets and also fit the ICT platform. Personas of typical users were developed and scenarios were created to describe typical TK interactions (first visit, profiling, regular usage and relapse). TK v1.0 was developed based on these specifications and the content on self-regulation, emotion and stress regulation was developed based on theoretically-informed logic models. TK v1.0 was tested extensively during development by expert users and formally in a feasibility study with users. Based on the results of the feasibility study and input from the consortium, the TK was refined and translated, yielding TK v2.0 in English, Danish and Portuguese.

The TK consists of a dashboard and personal project map to guide users sequentially through the content, which differs by intervention arm in the NoHoW trial. Therefore, there are four variants of the TK: (i) generic content (control), (ii) self regulation/motivation, (iii) emotion regulation, (iv) self regulation/motivation plus emotion regulation. Users receive a weekly email reminder to access the TK, and are instructed to always wear their activity trackers, and weigh themselves at least twice weekly. After logging into the TK, users arrive at the TK dashboard, which provides an overview of their individual data (steps and sleep from activity trackers, weight from wireless scale, mood and healthy eating self-reports, diary), as well as links providing additional help related to the specific content of each of the four versions. TK content is presented through short text articles, videos, quizzes, mini-apps and reflections. The content is accessed from the dashboard through the personal project map. Users receive a suggested order of modules in their weekly emails, but they have access to all TK content so they can choose which modules to visit (and re-visit). Accessing the TK is recommended once a week, but users can choose to access it as often as they like.

TEAM

WP2 is led by Prof. Pedro Teixeira, Dr. António Palmeira and Dr. Marta Marques (FMH) together with Dr. Miikka Ermes (VTT). The teams of Prof. Berit Heitmann (RH), Dr. David Nutter and Dr. Graham Horgan (James Hutton Institute, JHI), Prof. Falko Sniehotta (UNEW), Dr. Marcela Matos (UDC), Prof. James Stubbs (UNIVLEEDS), Dr. Paul Sacher (SW) and Mr. Ciaran Clissmann (Pintail Ltd, PT) actively contributed to the TK development and implementation.
**WP3/4 - Intervention Design, Set-up and Delivery**

**AIMS**

WPs 3 and 4 are dedicated to designing, setting up and delivering the NoHoW RCT, which includes:

- developing a full trial protocol (including standard operating procedures (SOPs) and supporting documentation),
- harmonising the trial components across trial sites in the UK, Denmark and Portugal,
- obtaining relevant ethical approvals for all trial sites,
- conducting a pilot of the trial to assess the suitability of the trial procedures, and
- conducting the NoHoW RCT (recruitment, baseline and follow-up measures).

**ACHIEVEMENTS**

The NoHoW trial is a three-centre four-arm, 2 x 2 factorial RCT. There are four arms that correspond directly to four versions of the TK: 1) Control group: self-weighing + no access to TK-specific content (only generic content), 2) self-weighing + self-regulation and motivation TK content, 3) self-weighing + emotion/stress regulation TK content, and 4) self-weighing + self-regulation, motivation and stress/emotion regulation TK content. The trial tests three hypotheses: (i) the impact of self regulation and motivation, (ii) the impact of emotion regulation/stress management on WLM, and (iii) possible interactions between self regulation/motivation and emotion regulation/stress management.

The trial population is overweight/obese adults (> 18 years) who have lost ≥ 5% of their weight in the last 12 months and had a BMI ≥ 25 kg/m² prior to weight loss. Health, biomarker, psychosocial and user experience measures will be taken at four time points (baseline, 6, 12 and 18 months). Primary outcomes are body weight and biomarkers (blood pressure, blood lipids, HbA1c and long-term cortisol levels from hair samples), assessed at 12 months. Secondary outcomes include physical activity, dietary intake, self-regulation, autonomous motivation, stress, well-being, quality of life, health economics analysis and process evaluation. 1,533 participants will be recruited across the three sites to retain 1,002 for the primary outcome measures.

A full trial protocol, with associated SOPs and supporting documentation, was developed by the trial lead in Leeds (UNIVLEEDS) in collaboration with the trial teams in RH (Copenhagen) and FMH (Lisbon), and the biostatistical team in JHI. Expert input was also contributed by the UNEW team, based on their experience in the NuLevel weight maintenance trial, and the SW team, based on their experience developing successful commercial weight management programmes. Evidence from the literature, WP1 and WP2 also informed development of the trial design. The full trial protocol has been approved by local ethics committees in Leeds, Copenhagen and Lisbon.

A 1-month pilot of the full protocol was initiated at all three sites in Dec 2016. 34 participants were recruited using the recruitment strategies and eligibility criteria as in the main trial. Interested respondents were screened and those eligible were consented and attended the baseline clinical visit. They were given access to the TK (and trained in its use) and issued activity trackers and wireless scales. Some technical and procedural issues arose and solutions were identified. For example, the protocol initially included a separate training day for the TK one week after the baseline visit, but there was sufficient time to complete the TK training at the baseline visit. To reduce the number of times participants attend the trial site, the protocol has been amended to deliver the TK training at the baseline visit, with the option for participants to return for additional training at their own request. Results of the pilot were analysed and reviewed by the independent Trial Steering Committee. Where necessary, changes to the protocol were submitted for ethics approvals.

**ON-GOING WORK**

The main trial was initiated at all sites in Mar 2017, following approval of ethics amendments.

**TEAM**

WPs 3/4 are led by Prof. James Stubbs and Dr. Sarah Scott (UNIVLEEDS). Trial sites in Lisbon are overseen by Prof. Pedro Teixeira and Dr. António Palmeira (FMH) and in Copenhagen by Prof. Berit Heitmann and Dr. Sofus Larsen (RH). Dr. David Nutter and Dr. Graham Horgan (JHI) developed and maintain the datahub and provide statistical expertise. Dr. Emma Foster and her team (UNEW) implemented INTAKE24 (online dietary measure) and Prof. Falko Sniehotta and Dr. Elizabeth Evans (UNEW) contributed expertise from the NuLevel trial.
WP5 - Data Management and Analysis

AIMS

WP5 is dedicated to:

- providing a central data storage facility for all RCT data and ensuring secure storage for the project duration and a further 20 years,
- receiving and depositing data during the trial and making it available to researchers for analysis,
- developing individualised prediction models to provide feedback to RCT participants about their weight management, and
- conducting statistical analyses of the RCT data, including health economics analysis.

ACHIEVEMENTS

JHI have developed a secure central data storage facility (data hub) for all data from the NoHoW RCT. The data hub also hosts the software associated with providing data to the TK and to trial staff, as well as hosting the TK and managing automated feedback emails to participants. The consortium has mapped the data sources and required data flows necessary to provide RCT participants with access to the TK, collect data from participant devices (via device supplier Fitbit), collect data from clinical visits and questionnaires (via the Qualtrics online questionnaire platform, EasyTrial trial management software and INTAKE24 dietary intake software). Based on this, the team in JHI has designed a database schema to meet the project requirements and secure data transfer protocols to ensure efficient data exchange between the data sources and the central data hub.

Prediction models for individualised feedback to participants in arms 2 and 4 of the trial have also been developed. The aim of this feedback is to use body weight, activity, TK usage data and Fitbit data to identify patterns that may help participants manage their weight better. This feedback depends on TK and activity tracker use, on participants weighing themselves frequently and on individual level associations being detected between behaviour and weight change. If these conditions are met, a message will be shown on the TK dashboard, such as ‘Your weight management seems better at weekends.’

Delivery of the RCT pilot (WP3) was supported by WP5. Technical issues related to data transfer, email delivery, etc. were flagged by the trial teams and resolved by JHI.

ON-GOING WORK

WP5 will collect and store data from the main trial (WP4), which was initiated in March 2017. Data to manage participants in the trial, will be provided to the trial teams as needed, as will troubleshooting of any issues that may arise during data transfer. The individualised prediction models will also continue to run throughout the trial.

Statistical analysis of the trial results will begin when the trial is completed.

TEAM

WP5 is led by Dr. Graham Horgan and Dr. David Nutter (JHI). Prof. Berit Heitmann (RH), Dr. António Palmeira (FMH) and Prof. James Stubbs (UNIVLEEDS) provide links to the trial sites in Copenhagen, Lisbon and Leeds. As the technology developers of the TK, Dr. Miikka Ermes and his team (VTT) provide essential inputs and expertise to WP5.
WP6 - Exploitation and Impact

AIMS

WP6 is dedicated to ensuring that NoHoW outputs are used to develop commercial weight loss maintenance products and services to address the obesity epidemic. This will be achieved by:

- integrating successful elements/strategies from NoHoW into the existing online weight management programme of our commercial partner, Slimming World™ (SW),
- exploring potential mechanisms to make TK v2.0 available to other commercial entities and stakeholders after the RCT is complete, and
- creating international networks of communication and practice to link and promote a new generation of WLM services.

ACHIEVEMENTS

Exploitation and impact have been a focus throughout the project to date, with SW and EASO having input into the design of the TK (WP2) and contributing to evidence building (WP1). In WP6, we have established processes for identifying and managing intellectual property (IP) arising from the project, including the establishment of an IP-sub-committee and IP register. Planning for the integration of successful elements/strategies from NoHoW into SW’s online weight management service has been initiated at project meetings. A face-to-face workshop for TK content developers (FMH, UDC, RH, UNIVLEEDS) and SW is planned for June 2017.

An Exploitation Workshop has also been held (Feb 2017), where IP rights (IPR) management was discussed. The workshop also included a stakeholder mapping exercise, led by EASO, where we identified key stakeholders for our exploitation and impact activities. We rated our current engagement with these stakeholders and set targets for future engagement. Communication channels and activities to best reach our target audience were also identified.

Through EASO and partner networks we are beginning to build a network of communication and practice in the area of WLM services. For example, EASO and FMH have organised a NoHoW workshop at the upcoming ECO 2017 meeting (May 2017).

ON-GOING WORK

WP6 will continue to plan and prepare for commercial exploitation of NoHoW outputs, identifying ways that NoHoW can enhance the SW online weight management service and developing a business plan for making TK v2.0 available after the NoHoW RCT. Activities to grow our WLM network will also continue through a variety of mechanisms (videos, targeted communications, sponsored symposia, etc.).

TEAM

WP6 is led by Dr. Paul Sacher (SW) and involves the participation of TK developers led by Dr. António Palmeira (FMH), Dr. Marcela Matos and Cristiana Duarte (UDC) and Dr. Miikka Ernes (VTT), Prof. Berit Heitmann (RH) and Prof. James Stubbs (UNIVLEEDS). Dr. Graham Horgan (JHI) provides expertise in individualised prediction modelling and data management/analysis. The teams of Mr. Euan Woodward (EASO) and Mr. Ciaran Clissmann (PT) bring expertise in stakeholder engagement and exploitation planning, respectively.
WP7 - Dissemination and Communication

AIMS

WP7 focuses on outward-facing communications and dissemination of the project to a broad range of key stakeholders, including the general public, patient groups, scientific community, policy makers, health professionals, industry, consumer organisations and the media. Practical tools and engaging materials tailored to specific groups are developed to communicate the project aims and results, alongside academic publications and conference presentations. WP7 also collaborates with WP6 to develop an audience for the commercial outputs of the project.

ACHIEVEMENTS

Activities to date have focused primarily on communicating and disseminating the aims of the project through a variety of means:

• A logo and ‘corporate’ brand for the project have been developed.
• The project website (www.nohow.eu) and social media accounts (twitter: @NoHoWH2020; facebook @nohowh2020) have been launched and actively maintained to grow our following, building an audience for our emerging and future results.
• To promote the project to lay audiences, a project flyer and ‘explainer’ video have been produced and shared via the website and social media.
• NoHoW researchers have presented the project to members of the EASO patient council and others at the European Congress on Obesity (ECO) 2015 and ECO 2016. Presentations to introduce the project and present initial results have also been made at a number of academic conferences (ASO UK Congress on Obesity, Danish Association for Study of Obesity Conference, UK Society for Behavioural Medicine Annual Meeting, UCL Centre for Behaviour Change Digital Health Conference and more).
• The team also issued a press release at the project kickoff and have continued engagement securing print, radio and television coverage in Denmark and Portugal.
• An initial e-newsletter was circulated to over 22,000 subscribers to the EASO mailing list to introduce the project.

ON-GOING WORK

WP7 will continue to communicate and disseminate the project through established channels, working to further expand our audiences and reach. For example, we will soon release Danish and Portuguese versions of the ‘explainer’ video and a follow-up e-newsletter.

TEAM

WP7 is led by Mr. Euan Woodward and Ms. Sheree Bryant (EASO) and involves the participation of all partners.