The LIGHT study: A Cognitive Behaviour Therapy based lifestyle tool to reverse type 2 diabetes

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1. To identify the perceived barriers and facilitators for initiating and maintaining a healthy lifestyle in people with both DM2 and a low SEP. 2. To co-create a digital, personalised CBT lifestyle tool together with end users (people with DM2) to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON57168

Source
ToetsingOnline

Brief title
The LIGHT study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, Type 2 Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Diabetes Fonds TKI toeslag opgebouwd vanuit Health Holland-PPS constructie

Intervention

Keyword: Cognitive Behaviour Therapy, Lifestyle, Psychology, Type 2 Diabetes

Outcome measures

Primary outcome

The primary outcome will be lifestyle behaviour (diet, physical activity,

stress and sleep).

Secondary outcome

proxies for lifestyle/behaviour change/health: willingness to change, BMI, and

quality of life

Study description

Background summary

The prevalence -and incidence- of diabetes mellitus type 2 (DM2) is rising and has reached the status of a global pandemic. Several studies demonstrated that strict lifestyle regimes can lead to a remission of DM2. Although possible, reversing DM2 is not easy. When trials with intensive lifestyle support end, people typically return to old, deeply ingrained, lifestyle habits. Several reasons for this failure to maintain an optimal lifestyle (including healthy diet, optimal physical activity, sleep and stress) include lack of motivation, lack of support and lack of adequate coping skills. These underlying psychological barriers often differ between people, and a targeted -more personalised- intervention addressing these barriers could be the key to improving lifestyle behaviours. Of note, despite DM2 disproportionally affecting people with a low socio-economic position (SEP), data is particularly lacking in this group.
Although psychological barriers in sustaining a healthy lifestyle have been assessed before, the problems that people with DM2 face are likely unique. In particular, people with DM2 have a much higher prevalence of complications and psychological co-morbidities such as emotional eating, depression, and psychological distress compared to a healthy population. These psychological factors likely prevent people with DM2 from following a healthy lifestyle, and need to be tackled in intervention strategies, especially at the individual level. Cognitive Behaviour Therapy (CBT) is a tool that could address this.
CBT is a type of psychotherapy that aims to change dysfunctional thoughts about

self-image and maladaptive cognitions and behaviour into more realistic ones. It has previously been shown to be effective in treating clinical depression and eating disorders. It furthermore managed to promote a sustainable weight loss, which is a key factor in reversing DM2.
Preventing a relapse to old habits has been the most difficult challenge in promoting a lifestyle change in people with DM2 and this could be effectively tackled with CBT. However, in order to do this, we need to identify which psychological factors are important in lifestyle behaviours in the first place. Therefore, we will first assess these barriers and facilitators, before developing a digital, personalised CBT tool on the platform of Greenhabit B.V. to improve lifestyle behaviours in people with DM2. In particular we will focus on people with a low SEP, as these have been understudied so far. To promote acceptability of the tool and increase the chances of success, it will be developed in co-creation sessions together with people with DM2.

Study objective

1. To identify the perceived barriers and facilitators for initiating and maintaining a healthy lifestyle in people with both DM2 and a low SEP.
2. To co-create a digital, personalised CBT lifestyle tool together with end users (people with DM2) to promote healthy lifestyle behaviours.

Study design

We will design a quantitative cross-sectional study to collect questionnaire data on demographic, social, clinical and psychological determinants of lifestyle behaviours of people with DM2. We will also conduct a qualitative study to collect more in-depth interview data on psychological determinants of lifestyle behaviours in individuals with DM2 and low SEP. These designs will be used to identify the perceived barriers and facilitators for initiating and maintaining a healthy lifestyle in people with DM2 and low SEP.
Based on input from these studies, the CBT lifestyle intervention tool will be created in collaboration with study participants in several co-creation sessions. The CBT lifestyle intervention tool will be built into the Greenhabit platform. In addition, we will generate recommendations for co-creation tools using the experience of the study participants in this study.

Intervention

The intervention will be a collaboratively developed CBT lifestyle tool to promote lifestyle behaviour changes in people with Type 2 Diabetes with low SEP on the platform of the company Greenhabit B.V.. (greenhabit.nl)
The CBT lifestyle tool will be integrated into their Artificial Intelligence (AI)-based platform to influence lifestyle behaviour. CBT elements will be included in the Greenhabit app. The topics that can be included and the design will be determined based on results from the questionnaire study, interview

study and co-creation sessions.

Greenhabit will make its lifestyle intervention platform available to study participants free of charge. The app personalises interventions (e.g. messages, challenges, quizzes, recipes) based on user-reported data such as quality of life, BMI and glucose levels. Due to privacy rules, this data is only available to participants. The company will not share this data, only the frequency of use of the platform by the participant will be shared.

A pilot RCT will be designed with an intervention and a control arm. The CBT tool will be incorporated into the Greenhabit platform before it is offered to a random sample of 30 study participants with DM2 and a low SEP. The program will last 12 weeks. Controls (n=30) will continue to receive their usual care, but will be asked to complete the same questionnaires and measurements as the intervention group. We will collect data using questionnaires, EMA methods, wearables (Freestyle Libre, accelerometers), and anthropometric measurements (e.g. weight). Therewith, we will collect data on both the participant and the tool. Among others, we will collect data on participant characteristics, lifestyle behaviours, and health, and the use and acceptability of the tool. This would not only allow us to identify which within-person factors determine lifestyle behaviours, but also assess the strength of these associations over time.
Additionally, we will assess which between-person factors may lead to differences in effectiveness (see Table 2, e.g. psychological factors, social and contextual factors). This will be done by including interaction terms and performing stratified analyses for groups with and without underlying psychological barriers (such as comorbidities, life-events or depression) that may be particularly detrimental in them adopting a healthy lifestyle. Thus, we can assess if there are differences between groups in the intervention's effectiveness.
Baseline demographics such as age, sex and age of diagnosis, will be collected at week 1 only. Questionnaires on psychological factors (e.g. optimism and depression), diabetes-specific variables (e.g. medication use), and diet will be conducted at week 1 and 12. EMA methods will be used to collect intensive longitudinal data on individual (e.g. positive emotions) and social/contextual factors (e.g. external stressors) 3 times a day for 7 days at week 1 and 12. This data will be used to generate individual temporal networks74 for each patient, which will be used to further personalize their individual CBT tool. Objective data will be collected at week 1 and 12 for 5-7 days. This will cover anthropometrics (e.g. weight and body composition, as measured by a scale), lifestyle behaviours (physical activity, sleep, as measured by an accelerometer) and glycemic control (defined as time in range and glycemic variability, as measured by a flash glucose meter). Lastly, we will examine the acceptability, usability, and feasibility of and participant satisfaction with the developed CBT tool at week 6 and 12 with validated questionnaires and at week 12 with semi-structured interviews. Tables 2-4 show an overview of the

measurements in the pilot RCT.

Study burden and risks

(Potential) Risks: we expect no risk for participants taking part in this study. Time investment is what we ask from the study participants. Participation in this study is entirely voluntary, and participants have the autonomy to decline or choose not to answer any of the questions posed to them.

Benefits: After successful completion of the questionnaire, participants will be offered to participate in hybrid (free) workshops where we will provide lunch. Participants of the interview study will receive a gift card of 15 euros. During the co-creation sessions, participants will have the chance to connect with other people with the same disease and share tips. Furthermore, if they participate in at least 1 co-creation session, they will receive 25 euros and travel costs reimbursed. Newsletters will be shared with participants to inform them.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Type 2 diabetes
- Age 18 years or older
- Fluent in Dutch or English
- (Recruitment will focus on low SEP, but other SEP groups will be included to compare groups. We will not advertise openly to participants to recruit low SEP, since this is stigmatising)

Exclusion criteria

no specific exclusion criteria other than the opposite of the inclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-09-2024
Enrollment:	1100
Type:	Anticipated

Ethics review

Approved WMO Date:	17-09-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87355.028.24