Clinical Study Protocol

The effectiveness of smartphone app guided interval-walking training compared to continuous aerobic walking training for people with type 2 diabetes or prediabetes. A pilot study.

Short title: Smartphone app guided interval-walking training for people with T2D or prediabetes.

Study Type:	Pilot study
Study Categorisation:	A
Study Registration:	Primary Registry of the WHO Registry Network (http://www.who.int/ictrp/network/primary/en/)
Study Identifier:	-
Principal Investigator:	Franziska Voigt, Physiotherapist cand MScPT Giesshübelstrasse 94 8045 Zürich Mobile: 0041 789752291 E-Mail: franziska.voigt-riel@web.de
Investigational Product:	None
Protocol Version and Date:	Version 1.1, 17/12/2018

Signature Page(s)

Study number	2018-02061
Study Title	The effectiveness of smartphone app guided interval-walking training compared to continuous aerobic walking training for people with type 2 diabetes or prediabetes. A pilot study.

The Sponsor has approved the protocol version 1.1, 17/12/2018 and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, ICH-GCP guidelines or ISO 14155 norm if applicable and the local legally applicable requirements.

Sponsor:

Gesundheitspraxis Löwen Center AG
José van der Hoef
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6004 Luzern
Phone: 00 41 41 410 69 40
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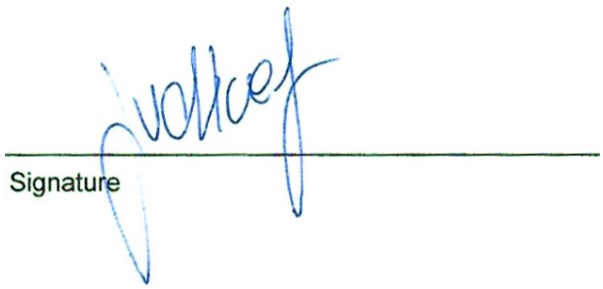
Luzern, 17/12/2018
Place/Date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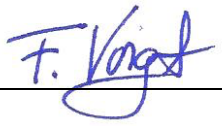
Local Principal Investigator at study site:

I have read and understood this trial protocol and agree to conduct the trial as set out in this study protocol, the current version of the World Medical Association Declaration of Helsinki, ICH-GCP guidelines or ISO 14155 norm and the local legally applicable requirements.

Site	Gesundheitspraxis Löwen Center AG Zürichstrasse 9 6004 Luzern Phone: 00 41 41 410 69 40 E-Mail: info@physio-luzern.ch
Principal investigator	Franziska Voigt, Physiotherapist cand MScPT

Luzern, 17/12/2018
Place/Date


Signature

The Master Thesis Tutor has approved the protocol version 1.1, 17/12/2018 and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, ICH-GCP guidelines or ISO 14155 norm if applicable and the local legally applicable requirements.

Master Thesis Tutor:

Dr. Ute Seper

Pinkafeld, 17/12/2018 — Ute Seper

Place/Date — Signature

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STUDY SYNOPSIS

Sponsor / Sponsor-Investigator	Gesundheitspraxis Löwen Center AG José van der Hoef Zürichstrasse 9 6004 Luzern Phone: 00 41 41 410 69 40 E-Mail: jose@physio-luzern.ch
Study Title:	The effectiveness of smartphone app guided interval-walking training compared to continuous aerobic walking training for people with type 2 diabetes or prediabetes. A pilot study.
Short Title / Study ID:	Smartphone app guided interval-walking training for people with T2D or prediabetes.
Protocol Version and Date:	Version 1.1, 17/12/2018
Trial registration:	The study is intended to be registered at the WHO Registry Network (http://www.who.int/ictrp/network/primary/en/).
Study category and Rationale	The patients will receive one of two standard rehabilitation programs. There are not exposed to an additional risk. Therefore the study is to be classified into category A.
Clinical Phase:	A pilot study.
Background and Rationale:	Obesity and metabolic disturbances, such as diabetes and prediabetes have reached an epidemic proportion worldwide (Kassi, Pervanidou, Kaltsas, & Chrousos, 2011). Besides dietary adaptations and medication, the major foundation in the clinical care of T2D is physical activity. PA has advantageous effects on glycaemic control and other key metabolic risk factors, as well as improvements in quality of life (Valentiner et al., 2017). Thereby, it has been suggested by several researchers, that interval endurance training is superior to continuous aerobic training (Karstoft et al., 2013, 2014; Maillard, Pereira, & Boisseau, 2018). Especially in terms of promoting a sustained lifestyle change for people with T2D, a simple yet highly effective way is a self-directed outdoor walking training (Byrne, Caulfield, & De Vito, 2017). Nowadays, smartphones are used as an assisting tool to control and monitor PA. Especially for people with T2D, smartphone applications improve the adherence in PA programs and are a beneficial tool for motivational support in a long-term increase in PA (Brinkløv et al., 2016; Byrne et al., 2017; Glynn et al., 2014; Ried-Larsen et al., 2016; Valentiner et al., 2017; Walker, Valentiner, & Langberg, 2018). Lately, a group of Danish researchers developed and evaluated an app called InterWalk (available in Danish only), which supports users during high intensity walking training, and found promising results (Brinkløv et al., 2016; Ried-Larsen et al., 2016; Valentiner et al., 2017). Therefore, smartphone assisted interval-walking training could be a feasible and low cost solution in order to fight the increasing number of people with T2D and prediabetes.

Objective(s):	The primary objective is to evaluate the feasibility of the study design with regard to comparing a smartphone app guided outdoor interval walking-training with a continuous aerobic walking training in patients with T2D/prediabetes. Secondary objectives are to investigate an effect of health-related quality of life, physical capacity and anthropometric measurements.
Outcome(s):	The primary outcome of this pilot study is to assess the feasibility of the processes that are key to the success of a large-scale study. The secondary outcome has the purpose to compare the effect between the smartphone app guided outdoor interval walking-training and continuous aerobic walking-training in terms of anthropometric measurements (WtHR, weight), aerobic capacity (6-MWT) and improvements in quality of life (SF-36).
Study design:	A pilot study in form of a randomized controlled trial (open-label, active control).
Inclusion / Exclusion criteria:	The aim is to include patients with type 2 diabetes or prediabetes diagnosed by a doctor. Main inclusion criteria are: The ability to walk 30 min continuously; No contraindication, which prohibit physical activity; The ability to talk and read German fluently; Owning a Smartphone (Apple / Android). The main exclusion criteria are: The inability to follow the procedures of the study, e.g. due to language problems, psychological disorders, dementia, etc. of the participant; Contraindication, which prohibit physical activity (e.g. uncontrolled arterial hypertension, limited cardiac insufficiency); Limiting musculoskeletal disorders who makes a participation not possible (Injury in the lower limbs).
Measurements and procedures:	The goal is to include at least 20 patients. The interval-walking group, containing 10 individuals, is going to complete a smartphone app guided walking training for 4 weeks. The other 10 participants are executing a continuous walking training (control group) for 4 weeks. All participants will undergo a screening by a local general practitioner. After they are diagnosed with T2D or prediabetes, participants are sent to GLC. In case they fulfil the inclusion and exclusion criteria, there is a randomization by computer in order to select the patients to one of the two training groups. After randomization the two groups will be trained differently as described above.
Study Product / Intervention:	The smartphone app assisted interval-walking group is going to complete a walking training of 30 minutes, 3 times per week for 4 weeks. The intervals are containing blocks of 3 minutes of high intensity / fast walking, followed by 3 minutes of lower intensity / slower walking. The training is guided by a PT 2 times per week und once per week the individual has to perform the training on his/her own (preferable on the weekend).
Control Intervention (if applicable):	The continuous walking group (control group) is going to walk 30 minutes at a medium pace 3 times per week for 4 weeks. The training is guided by a PT 2 times per week und once per week the individual has to perform the training on his/her own (preferable on the weekend).
Number of Participants with Rationale:	The aim is to include at least 20 participants for this study. There is no power analysis necessary, because it is a pilot study.

Study Duration:	• From July 2017 – June 2018 (actual testing: March – April 2019)
Study Schedule:	March 2018 First-Participant-In (planned) April 2018 Last-Participant-Out (planned)
Investigator(s):	Franziska Voigt, Physiotherapist cand MScPT Giesshübelstrasse 94 8045 Zürich Mobile: 0041 789752291 E-Mail: franziska.voigt-riel@web.de
Study Centre(s):	Single-centre
Statistical Considerations:	The effect of the primary and secondary outcome will be tested with quantitative statistics. There is no power calculation necessary for the sample size, because it is a pilot study.
GCP Statement:	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements.

ABBREVIATIONS

AE	Adverse Event
BASEC	Business Administration System for Ethical Committees, (https://submissions.swissethics.ch/en/)
CA	Competent Authority (e.g. Swissmedic)
CEC	Competent Ethics Committee
CRF	Case Report Form
ClinO	Ordinance on Clinical Trials in Human Research *(in German: KlinV, in French: OClin, in Italian: OSRUm)*
eCRF	Electronic Case Report Form
CTCAE	Common terminology criteria for adverse events
DSUR	Development safety update report
GCP	Good Clinical Practice
GLC	Gesundheitspraxis Löwen Center
GP	General Practitioner
IB	Investigator's Brochure
Ho	Null hypothesis
H1	Alternative hypothesis
HRA	Federal Act on Research involving Human Beings *(in German: HFG, in French: LRH, in Italian: LRUm)*
IMP	Investigational Medicinal Product
IIT	Investigator-initiated Trial
ISO	International Organisation for Standardisation
ITT	Intention to treat
MD	Medical Device
MedDO	Medical Device Ordinance *(in German: MepV, in French: ODim)*
PA	Physical activity
PI	Principal Investigator
PT	Physiotherapist
SDV	Source Data Verification
SOP	Standard Operating Procedure
SPC	Summary of product characteristics
SUSAR	Suspected Unexpected Serious Adverse Reaction
T2D	Type 2 Diabetes
TMF	Trial Master File
WtHR	Waist-to-Height Ratio
6-MWT	Six-minutes walk test

STUDY SCHEDULE

1. STUDY ADMINISTRATIVE STRUCTURE

1.1 Sponsor

Gesundheitspraxis Löwen Center AG

José van der Hoef

Zürichstrasse 9

6004 Luzern

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E-Mail: jose@physio-luzern.ch

The Sponsor supervises the study (data collection, management, data analysis and interpretation of the data).

1.2 Principal Investigator(s)

Franziska Voigt

Physiotherapist cand MScPT

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The Principal Investigator maintains written quality procedures to ensure that the clinical investigation is designed, conducted and monitored according to Good Clinical Practice (GCP). The Principal Investigator defines the roles and responsibilities of the study team. The Principal Investigator ensures documentation of training, experience and clinical knowledge of all relevant parties. The Principal Investigator submits the applications to the Competent Ethics Committee (CEC) for review and approval and ensures that these approvals are obtained and documented. Furthermore the principal Investigator also implements and manages the execution of the clinical study and ensures data integrity and the rights, safety and well-being of the subjects involved in the study. This study will be the master thesis of the Principal Investigator and there is no external funding. The master degree program is called: “Advanced Physiotherapy and Management” and takes place in Eisenstadt/Vienna, Austria.

1.3 Statistician ("Biostatistician")

Statistical analysis will be carried out by PI.

1.4 Laboratory

Laboratory exams are not performed in the setting of this trial.

1.5 Monitoring institution

No external monitoring institution according to KlinV Art. 5. There is no extent for risk, because it is part of routine care.

1.6 Data Safety Monitoring Committee

Since only a limited set of data is assessed in this pilot study, no Data Safety Monitoring Committee will be part of the study team. Clinical data obtained during the study are also used for routine care and will only be accessible to the study team (responsible PT, PI). The data will be stored in a locked cabinet in two folders. Folder A will include the randomisation-list, folder B will include the CRF and the USB-stick with pseudonymous data. The data will be archived for 10 years.

1.7 Any other relevant Committee, Person, Organisation, Institution

Master Thesis Tutor:

MMag. Dr. scient. med. Ute Seper

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The Master Thesis Tutor is the head of the PI's master thesis program and is giving assistance in the process of writing the master thesis.

2. ETHICAL AND REGULATORY ASPECTS

The decision of the CEC and Swissmedic/foreign competent authority concerning the conduct of the study will be made in writing to the Sponsor-Investigator before commencement of this study. The clinical study can only begin once approval from all required authorities has been received. Any additional requirements imposed by the authorities shall be implemented.

2.1 Study registration

The study is intended to be registered at the WHO Registry Network (http://www.who.int/ictrp/network/primary/en/).

2.2 Categorisation of study

This clinical trial comes under Category A, because it is routine care and recognised as standard in guidelines prepared in accordance with internationally accepted quality criteria.

2.3 Competent Ethics Committee (CEC)

The Sponsor-Investigator will obtain approval from the CEC before the start of the study. Any change in the clinical study protocol will be submit to the Sponsor and the CEC.

Premature study end or interruption of the study is reported within 15 days. The regular end of the study is reported to the CEC within 90 days, the final study report shall be submitted within one year after study end. Amendments are reported according to chapter 2.10.

2.4 Competent Authorities (CA)

Not applicable.

2.5 Ethical Conduct of the Study

The study will be carried out in accordance to the protocol and with principles enunciated in the current version of the Declaration of Helsinki, the guidelines of Good Clinical Practice (GCP) issued by ICH, in case of medical device: the European Regulation on medical devices 2017/745 and the ISO Norm 14155 and ISO 14971, the Swiss Law and Swiss regulatory authority's requirements. The CEC and regulatory authorities will receive annual safety and interim reports and be informed about study stop/end in agreement with local requirements.

2.6 Declaration of interest

There is no conflict of interest. The Sponsor-Investigator does not hold any intellectual, financial or proprietary interests in the procedure of this study. The study is part of the Master Thesis of the PI.

2.7 Patient Information and Informed Consent

The investigators will explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent medical assistance and treatment.

The participant must be informed that his/her medical records may be examined by authorised individuals other than their treating physician.

All participants for the study will be provided a participant information sheet and a consent form describing the study and providing sufficient information for participant to make an informed decision about their participation in the study. Potential participants are usually informed at the date of admission to the GLC about the study and will have at least 24 hours to decide whether they are interested in participating or not.

The patient information sheet and the consent form will be submitted to the CEC to be reviewed and approved. The formal consent of a participant, using the approved consent form, must be obtained

before the participant is submitted to any study procedure.

The participant should read and consider the statement before signing and dating the informed consent form, and should be given a copy of the signed document. The consent form must also be signed and dated by the investigator (or his designee) at the same time as the participant sign, and it will be retained as part of the study records.

2.8 Participant privacy and confidentiality

The investigator affirms and upholds the principle of the participant's right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals.

Individual subject medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited. Subject confidentiality will be further ensured by utilising subject identification code numbers to correspond to treatment data in the computer files.

For data verification purposes, authorised representatives of the Sponsor, namely the PI, or the CEC may require direct access to parts of the medical records relevant to the study, including participants' medical history.

2.9 Early termination of the study

The Sponsor-Investigator may terminate the study prematurely according to certain circumstances, for example:

- Ethical concerns,
- Insufficient participant recruitment,
- When the safety of the participants is doubtful or at risk, respectively,
- Alterations in accepted clinical practice that make the continuation of a clinical trial unwise,
- Early evidence of benefit or harm of the experimental intervention

2.10 Protocol amendments

Amendments to the study protocol can only be carried out by the PI or Sponsor-Investigator, regarding the criteria mentioned below.

Substantial amendments are only implemented after approval of the CEC and CA respectively.

Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of human subjects may proceed without prior approval of the sponsor and the CEC/CA. Such deviations shall be documented and reported to the sponsor and the CEC/CA as soon as possible.

All non-substantial amendments are communicated to the CA as soon as possible if applicable and to the CEC within the Annual Safety Report (ASR).

3. BACKGROUND AND RATIONALE

3.1 Background and Rationale

Obesity and metabolic disturbances, such as diabetes and prediabetes have reached an epidemic proportion worldwide (Kassi et al., 2011). According to the World Health Organization (WHO), 347 million people have diabetes and due to the raising incidences it will be the seventh leading cause of death by 2030 (Yach & Alberti, 2003). Especially the high impact on the health care system and on the individuals themselves, is regarded as a serious health issue (Yach & Alberti, 2003; Zhou et al., 2014).

Besides dietary adaptations and medication, the major foundation in the clinical care of type 2 diabetes (T2D) is physical activity (PA). PA has advantageous effects on glycaemic control and other key metabolic risk factors, as well as improvements in quality of life (Valentiner et al., 2017). Thereby, it has been suggested by several researchers, that interval endurance training is superior to continuous aerobic training (Karstoft et al., 2013, 2014; Maillard et al., 2018). Especially in terms of promoting a sustained lifestyle change for people with T2D, a simple yet highly effective way is a self-directed outdoor walking training (Byrne et al., 2017).

Nowadays, smartphones are used as an assisting tool to control and monitor PA. Especially for people with T2D, smartphone applications improve the adherence in PA programs and are a beneficial tool for motivational support in a long-term increase in PA (Brinkløv et al., 2016; Byrne et al., 2017; Glynn et al., 2014; Ried-Larsen et al., 2016; Valentiner et al., 2017; Walker et al., 2018). Lately, a group of Danish researchers developed and evaluated an app called InterWalk (available in Danish only), which supports users during high intensity walking training, and found promising results (Brinkløv et al., 2016; Ried-Larsen et al., 2016; Valentiner et al., 2017). Therefore, smartphone assisted interval-walking training could be a feasible and low cost solution in order to fight the increasing number of people with T2D and prediabetes.

This leads to the following research questions:

Is a smartphone guided interval-walking training effective in terms of anthropometric measurements, aerobic capacity and improvements in quality of life for people with prediabetes or T2D?

Is it more effective in comparison to a continuous aerobic walking training?

Is it a beneficial, feasible and low cost tool as well as a motivational support for the individuals?

Current Guidelines for Diabetes care show, that interval and continuous walking training have a benefit for patients with T2D, hence neither of the groups would be potentially suffering from a disadvantage or be exposed to an additional risk due to the study. The Intervention groups could have the harm to perform the training under bad weather conditions.

The primary reason to conduct this study is to evaluate the feasibility of the study design and the effectiveness of smartphone app guided outdoor interval-walking training for patients suffering from T2D/prediabetes. The secondary purpose is to investigate an effect of health-related quality of life, physical capacity and anthropometric measurements in comparison to the control group.

3.2 Investigational Product (treatment, device) and Indication

No investigational product will be used in this study.

3.3 Preclinical Evidence

Not applicable to this study.

3.4 Clinical Evidence to Date

There was no clinical evidence concerning this subject obtained beforehand.

3.5 Dose Rationale / Medical Device: Rationale for the intended purpose in study (pre-market MD)

No drugs/medical device will be used.

3.6 Explanation for choice of comparator (or placebo)

A continuous aerobic walking training is a well-established training program for patients with T2D as shown in different studies.

3.7 Risks / Benefits

Current Guidelines for Diabetes care demonstrate, that interval and continuous walking-training have a benefit for patients with T2D, hence neither of the groups would be potentially suffering from a disadvantage or be exposed to an additional risk due to the study. It has been suggested by several researchers, that interval endurance training is superior to continuous aerobic training (Karstoft et al., 2013, 2014; Maillard et al., 2018). Therefore, the patients could perform an effective interval walking-training by themselves, whenever they have time and integrate it in their weekly routine. Since there is less dependence on facilities, exercise tools, fitness trainers or physiotherapists, costs paid both by the individuals concerned as well as the healthcare system can be largely reduced. This is of particular interest when considering that the number of T2D will massively rise, yet there won't be enough professionally trained staff to provide adequate treatment in terms of PA programs. So smartphone guided interval-walking programs could improve the physical capacity, reduce life-threatening cardio metabolic risk factors, decrease the consumption of medication and increase the quality of life of the individuals.

The training groups could have the harm to perform the training under bad weather conditions.

Before the participants are sent to the GLC, a GP is screening the patients for T2D/prediabetes and if there are any contraindications, which restrict the patient to perform physical activity. Patients are always under supervision of 2 PTs. The intervention group has the opportunity to learn to conduct a training method, which can be easily incooperated in daily life and does not need specific and expensive training equipment.

Because of the risk of hypoglycaemia, participants with long-term insulin and sulfonylurea treatment are excluded.

3.8 Justification of choice of study population

Patient Population: T2D and prediabetes

I have chosen patients with T2D and prediabetes, because they might benefit the most from smartphone app guided outdoor interval-walking training. An app represents an easy and feasible tool to increase the adherence of a physical activity program in patients with T2D and prediabetes. They can carry out this training method at home and this might provide long-term benefits in terms of increasing PA and reducing cardio metabolic risk factors. They could also experience an app as a motivational and feasible tool, which could guide and support them, since it is known that high intensity interval training, is a challenging and exhausting training method.

Patients will only be included in the study if they sign the informed consent documents themselves and they need to be in full competence of their consciousness.

Before the participants are sent to the GLC, a GP is screening the patients for T2D/prediabetes and if there are any contraindications, which restrict the patient to perform physical activity. If any signs of exacerbation of T2D (e.g. hyperglycaemia, hypoglycaemia), confirmed by a physician, occur the patient will be excluded of the study for safety reasons. If a patient shows tendency to fall or has vertigo he will be excluded of the study. Because of the risk of hypoglycaemia, participants with long-term insulin and sulfonylurea treatment are excluded.

4. STUDY OBJECTIVES

4.1 Overall Objective

The aim of this study is to evaluate the feasibility of the study design with regard to comparing a smartphone app guided outdoor interval walking-training with a continuous aerobic walking-training in patients with T2D/prediabetes. Secondary objectives are to investigate an effect of health-related quality of life, physical capacity and anthropometric measurements with interval walking-training.

Outdoor interval walking-training is a simple method of training, which the patient can be easily carried out at home and independently.

4.2 Primary Objective

The study seeks primarily to determine the feasibility of the study design with regard to comparing a smartphone app guided outdoor interval-walking training with a continuous aerobic walking training in patients with T2D/prediabetes.

4.3 Secondary Objectives

Secondary objectives are to estimate the effect of health-related quality of life, physical capacity and anthropometric measurements with interval-walking training.

4.4 Safety Objectives

Not applicable.

5. STUDY OUTCOMES

5.1 Primary Outcome

The primary outcome of this pilot study is to assess the feasibility of the processes that are key to the success of a large-scale study.
The feasibility factors of the study design are measured by reasons for exclusion, recruitment rate, reasons for dropouts, patients' satisfaction, intensity of the training method, missing data, estimated sample size. The feasibility factors will be measured during the whole study time and are assessed by descriptive statistics, questionnaires and interviews.

5.2 Secondary Outcomes

The secondary outcome has the purpose to compare the effect between the smartphone app guided outdoor interval walking-training and continuous aerobic walking-training in terms of anthropometric measurements (WtHR, weight), aerobic capacity (6-MWT) and improvements in quality of life (SF-36). These measurements will take place at baseline and after 4 weeks of training.

5.3 Other Outcomes of Interest

Another outcome of this study is the analysis whether patients experience an app as a motivational and feasible tool, which could guide and support them, since it is known that interval training is a challenging and exhausting training method. This will be investigated by a questionnaire and an interview after the 4-week training intervention.

5.4 Safety Outcomes

Not applicable.

6. STUDY DESIGN

6.1 General study design and justification of design

For the pilot study, a randomized controlled trial is planned. The goal is to include (at least) 20 patients with T2D or prediabetes, who are initially screened by a local GP and sent to GLC. The interval walking-group (intervention group), containing 10 individuals, is going to complete a smartphone app guided walking-training 3 times per week for 4 weeks. The other 10 participants are executing a continuous walking-training (control group) 3 times per week for 4 weeks.

After the participants are diagnosed with T2D or prediabetes by a GP, they are advised to participate in the Diamove program, which is a regular training program, specifically designed for patients with T2D or prediabetes, at GLC. Once they decide to join Diamove, patients are educated about the program and the study. It's sorely the patient's choice, which option they choose: Whether they join Diamove, participate in the study or both of them. This is done during the first contact at GLC. After they are willing to participate in the study, a PT is screening all participants for inclusion and exclusion criteria. If the patients are eligible for the study, they will receive informed consent. The patients have 24 hours time to sign it. The patients have to sign an informed consent form before entering the study. There is a randomization by a computer program (Research Randomizer: www.randomizer.org) in order to select the patients to one of the two training groups. After randomization the two groups will be trained differently as described above. All measurements happen at baseline and after the 4 weeks of training.

The 4-week intervention will not be funded. The time and expertise of the participating physiotherapists will be not charged.

6.2 Methods of minimising bias

6.2.1 Randomisation

The randomisation will be done by a computer program, which is called Research Randomizer (www.randomizer.org).

6.2.2 Blinding procedures

The participants are blinded to group allocation. They will be randomly assigned to one of the two training groups. It is not possible to blind the PT and patients during the training interventions.

6.2.3 Other methods of minimising bias

SF-36, 6MWT, weight and WtHR are outcome measures that are known to be valid and responsive for patients with diabetes.

6.3 Unblinding Procedures (Code break)

It is not possible to blind the PT, since he has to observe the training interventions. The participants are blinded to group allocation. During the training intervention participants are not blinded.

7. STUDY POPULATION

7.1 Eligibility criteria

Participants fulfilling all of the following inclusion criteria are eligible for the study:

- Informed Consent as documented by signature (Appendix Informed Consent Form)
- Individuals with type 2 diabetes or prediabetes diagnosed by a GP and referred to GLC
- Ability to walk 30 min continuously
- Ability to read and speak German fluently
- No contraindication, which prohibit physical activity
- Owning a smartphone (Apple / Android)

The presence of any one of the following exclusion criteria will lead to exclusion of the participant:

- Inability to follow the procedures of the study, e.g. due to language problems, psychological disorders, dementia, etc.
- Patients receiving long-term insulin and/or sulfonylurea treatment
- Contraindication, which prohibit physical activity (e.g. uncontrolled arterial hypertension, limited cardiac insufficiency)
- Limiting musculoskeletal disorders, which prohibit the participation (Injury in lower limbs, painful osteoarthritis etc.)
- No informed consent
- <18 years of age
- Medical contraindications to exercise

7.2 Recruitment and screening

The local collaborating GPs (Lumed Hausärzte) are screening patients for T2D/prediabetes. After the participants are diagnosed with T2D or prediabetes by a GP, they are advised to participate in the Diamove program, which is a regular training program, specifically designed for patients with T2D or prediabetes, at GLC. Once they decide to join Diamove, patients are educated about the program and the study. It's sorely the patient's choice, which option they choose: Whether they join Diamove, participate in the study or both of them. This is done during the first contact at GLC. After they are willing to participate in the study, the responsible PT is assessing them for inclusion and exclusion criteria. After the participants met the inclusion criteria and signed the Informed Consent, the initial testing will be executed by the PT. (Weight and WtHR will be measured, the 6-MWT will be conducted and the SF-36 will be filled out.)

According to the "Schweizerische Gesellschaft für Endokrinologie und Diabetologie" following criteria for the diagnosis of T2D / prediabetes have to be met:

1. Diagnosis of T2D: HbA1c > 6.5%, comparable to fasting plasma glucose > 7.0 mmol/l or a 2h-plasma glucose with oral glucose tolerance test (OGTT) > 11.1 mmol/l or a plasma glucose > 11.1 mmol/l with symptoms of hyperglycaemia.

2. Diagnosis of prediabetes: HbA1c of 5.7 – 6.4%, comparable to fasting plasma glucose of 5.6 – 6.9 mmol/l or a 2h-plasma glucose with OGTT of 7.8 – 11.1 mmol/l.

7.3 Assignment to study groups

The randomisation will be done by a computer program, which is called Research Randomizer (www.randomizer.org). Each incoming patient receives a number from 1 to 20 (depending on the order when he/she enters the GLC). After using the Research Randomizer, the numbers from 1 to 20 will be randomly allocated to one of the following 2: 1 = intervention group, 2 = control group.

7.4 Criteria for withdrawal / discontinuation of participants

Participants are discontinued from the study if they withdraw their informed consent or if significant safety concerns arise during the study. Drop-outs are not replaced by other subjects. The data obtained until the discontinuation of the participant are used for the analysis of this study.

8. STUDY INTERVENTION

8.1 Identity of Investigational Products (treatment / medical device)

8.1.1 Experimental Intervention

This pilot study investigates smartphone app guided interval outdoor walking-training in patients with T2D or prediabetes. The interval walking-group is going to complete a smartphone app guided walking training 3 times per week for 4 weeks.

8.1.2 Control Intervention (standard/routine/comparator treatment / medical device)

The control group is executing a continuous walking training, which is one of the recommended training methods for patients with T2D. According to the American College of Sports Medicine the recommended weekly activity for adults is at least 150 minutes of moderate-intensity exercise per week, which means 30-60 minutes of moderate-intensity exercise (five days per week) or 20-60 minutes of vigorous-intensity exercise (three days per week).

8.1.3 Packaging, Labelling and Supply (re-supply)

Not applicable.

8.1.4 Storage Conditions

Not applicable.

8.2 Administration of experimental and control interventions

8.2.1 Experimental Intervention

The smartphone app guided interval-walking group is going to complete a walking training of 30 minutes, 3 times per week for 4 weeks. The intervals are containing blocks of 3 minutes of high intensity / fast walking, followed by 3 minutes of lower intensity / slower walking.

The utilized smartphone app is: the Runkeeper app, which is used in order to track speed and time. Since the app was not designed for diabetes patients only, the handling of the app is different. The Runkeeper app is available in German and is free of charge, however, it does not offer a self-conducted initial fitness test and calculation of interval speed. Therefore, a 6-minute-walk test has to be conducted previously and intervals have to be calculated for every individual. During the interval-walking training, the participants have to observe the speed (km/h) and the time in order to conduct 3 minutes of high/lower intensity. The Borg scale is implemented as well, in order to verify the high und low intensity level. During high intensity intervals participants will be encouraged to aim a number form 15 – 18 and during lower intensity intervals a number form 10 – 14 on the Borg scale.

8.2.2 Control Intervention

The control group is executing a continuous walking training, which is one of the recommended training methods for patients with T2D. According to the American College of Sports Medicine the recommended weekly activity for adults is at least 150 minutes of moderate-intensity exercise per week, which means 30-60 minutes of moderate-intensity exercise (five days per week) or 20-60 minutes of vigorous-intensity exercise (three days per week).

In addition, a Borg scale will be applied during the walking training, in order to check the intensity of the individuals. Since the participants are encouraged to walk in a moderate intensity, a number from 12 – 14 on the Borg scale should be maintained during the walking training.

8.3 Dose / Device modifications

Not applicable.

8.4 Compliance with study intervention

Patients in both groups will carry out their training under supervision of 2 PTs 2 times per week (Tuesday and Thursday). Once per week the individual has to carry out the training on his/her own (preferable on the weekend).

If a patients refuses to carry out his training as instructed he will be kept in the study as it provides further data about the study`s feasibility, unless he denies his informed consent.

8.5 Data Collection and Follow-up for withdrawn participants

If a patients refuses to carry out his training as instructed he will be kept in the study as it provides further data about the study`s feasibility, unless he denies his informed consent.

8.6 Trial specific preventive measures

Except for the exclusion criteria listed above there are no trial-specific preventive measures.

8.7 Concomitant Interventions (treatments)

The patients receive a standard training program, which is advised in guidelines and in general diabetes care. We don't expect any specific impact on study objectives. As in general for the training with patients with T2D, some carbohydrates are stored and are in reachable distance (dextrose, cereal bars), in case a patient is showing signs of hypoglycaemia. In case of T2D, the patients is advised to measure blood glucose levels after the training and in case adapt the food intake (see informed consent.)

8.8 Study Drug / Medical Device Accountability

Not applicable.

8.9 Return or Destruction of Study Drug / Medical Device

Not applicable.

9. STUDY ASSESSMENTS

9.1 Study flow chart(s) / table of study procedures and assessments

9.2 Assessments of outcomes

9.2.1 Assessment of primary outcome

The primary outcome of this pilot study is to assess the feasibility of the processes that are key to the success of a large-scale study.
The feasibility factors of the study design are measured by reasons for exclusion (counting), recruitment rate (counting), reasons for dropouts (interview), patients' satisfaction (questionnaire und interview), intensity of the training method (evaluation with the help or the training protocol), missing data (training protocol), estimated sample size for a future study (calculated with GPower).

9.2.2 Assessment of secondary outcomes

The secondary outcome has the purpose to compare the effect between the smartphone app guided outdoor interval walking-training and continuous aerobic walking-training in terms of anthropometric measurements (WtHR, weight), aerobic capacity (6-MWT) and improvements in quality of life (SF-36). These measurements will take place at baseline and after 4 weeks of training.

9.2.3 Assessment of other outcomes of interest

Another outcome of interest of this study is the analysis whether patients experience an app as a motivational and feasible tool, which could guide and support them, since it is known that interval training is a challenging and exhausting training method. This will be investigated by a questionnaire and an interview after the 4-week training intervention.

9.2.4 Assessment of safety outcomes

Not applicable.

9.2.4.1 Adverse events

The participants receive a standard training program, which is advised in guidelines and in general diabetes care. The training will be adapted, so that every patient can execute it. When there are any signs of exacerbation of the condition of T2D, the patient will be send immediately to the GP.

9.2.4.2 Laboratory parameters

Not applicable.

9.2.4.3 Vital signs

Not applicable.

9.2.5 Assessments in participants who prematurely stop the study

Not applicable.

9.3 Procedures at each visit

Patients are supervised and instructed by 2 PTs 2 times per week, when they come to GLC in order to execute the training. They are no further procedure carried out.

9.3.1 Split into subtitles by type of visit

Week 1: Recruitment (inclusion / exclusion criteria)

9.3.2 Split into subtitles by type of visit

Week 1: Baseline measurements include quality of life (SF-36), physical capacity (6-MWT) and anthropometric measurements (weight, WtHR). Informed consent has to be filled out as well.

9.3.3 Split into subtitles by type of visit

Week 2-5: Smartphone app guided outdoor interval walking-training or outdoor continuous aerobic walking-training.

Week 6: Retesting: Quality of life (SF-36), physical capacity (6-MWT) and anthropometric measurements (weight, WtHR). Interview and questionnaire about feasibility.

10. SAFETY

10.1 Drug studies

This study is not a drug study.

10.1.1 Definition and assessment of (serious) adverse events and other safety related events

According to KlinV Art. 63, a serious adverse event is defined as any event, which requires inpatient treatment not envisaged in the protocol or extends a current hospital stay. We don't expect a life-threatening event.

10.1.2 Reporting of serious adverse events (SAE) and other safety related events

According to KlinV Art. 63, the ethic committee "Nordwest- und Zentralschweiz" (EKNZ) will be informed within 15 days. According to KlinV Art. 62, if immediate safety and protective measures have to be taken during the conduct of a clinical trial, the investigator have to notify the ethic committee "Nordwest- und Zentralschweiz" (EKNZ) of these measures, and of the circumstances necessitating them, within 7 days.

10.1.3 Follow up of (Serious) Adverse Events

Not applicable.

10.2 Medical Device Category C studies

Not applicable.

10.2.1 Definition and Assessment of (Serious) Adverse Events and other safety related events

Not applicable.

10.2.2 Reporting of (Serious) Adverse Events and other safety related events

Not applicable.

10.2.3 Follow up of (Serious) Adverse Events

Not applicable.

10.3 Medical Device Category A studies

No medical device used.

10.3.1 Definition and Assessment of safety related events

Not applicable.

10.3.2 Reporting of Safety related events

Not applicable.

11. STATISTICAL METHODS

11.1 Hypothesis

- Some adjustments in the feasibility of the study design are expected.
- A lager effect in the intervention group for quality of life, aerobic capacity and anthropometric measurements compared to the control group is expected (rejecting the null hypothesis).
- For a future study with a power calculation the same results on the statistical level of significance 0.05 are expected.

11.2 Determination of Sample Size

This project is a pilot study and one of the objectives is to determine parameters, which can be used in order to calculate sample size in future research projects. For this project a sample size of 10 (2 groups of 10 participants) was chosen.

11.3 Statistical criteria of termination of trial

Not applicable.

11.4 Planned Analyses

The feasibility factors of the study design are analysed by

- Reasons for exclusion
- Recruitment rate
- Reasons for drop out
- Patient's satisfaction with the intervention
- Intensity of the training methods
- Missing data
- Estimated sample size for a future large-scale study.

The quantitative data analysis will be done in Excel and JASP. Basic descriptive statistics are used for an explorative data analysis. Inference statistics will be calculated based on data distribution. Paired sample t-tests or repeated measures of ANOVA will be determined.

11.4.1 Datasets to be analysed, analysis populations

All randomised subjects.

11.4.2 Primary Analysis

The planned primary analysis concerns feasibility of the study design (see 11.4)

It will be started upon admission by PI and responsible PT and carried out continuously during the study. Final analysis will be executed by the PI after the termination of the final measurements.

11.4.3 Secondary Analyses

Secondary analysis includes the effects. Descriptive statistics and the statistical tests mentioned above will be carried out by the PI after the termination of the final measurements.

11.4.4 Interim analyses

No interim analysis is planned.

11.4.5 Safety analysis

No safety analysis is planned.

11.4.6 Deviation(s) from the original statistical plan

If any changes from the original statistical plan will occur, they will be mentioned in the final study report.

11.5 Handling of missing data and drop-outs

No drop-outs will be replaced and data obtained before the drop out will be analysed as described in the protocol.

12. QUALITY ASSURANCE AND CONTROL

The whole GLC team will be informed about the purposes and stages of the study in a meeting.

The PI will oversee the study and will be present in every session in order to guarantee a common level of quality.

All members of the study team are trained PT with permission to work in Switzerland, which guarantees a certain level of knowledge and training.

12.1 Data handling and record keeping / archiving

Obtained data will be stored on institutional computers and on patients' sheets. All study data are archived at the GLC for a minimum of 10 years.

12.1.1 Case Report Forms

The PI creates a paper CRF for each patient after inclusion in the study, using only the participant number for identification. The CRF will be filled out continuously during the study and handed in afterwards to the PI for analysis.

12.1.2 Specification of source documents

The source data are kept in the patient file. The source data include the demographic data, the informed consent and inclusion into the study, the participant number, the CRF, AE and other safety-related events as well as all other original study documents. The patient file is located in a folder in a closed cabinet during the treatment of the participant and will be stored in the GLC after the release of the patient from the inpatient rehabilitation.

12.1.3 Record keeping / archiving

All study data must be archived for a minimum of 10 years after study termination or premature termination of the clinical trial. The Data sheets are archived in two folders in a locked cabinet in the GLC. The electronic data are archived on a write-protected USB-stick and are locked in a cabinet in the GLC, too.

12.2 Data management

12.2.1 Data Management System

The study data will be entered into an electronic file and subsequently analysed using excel and is only accessible by the PI.

A datasheet with the patient`s demographics and distributed study number will be created in excel and stored safely. This is only accessible by the PI.

12.2.2 Data security, access and back-up

The electronic data can only be accessed by the PI and will be saved on a password-protected USB-stick. The USB-Stick will be backed up every day and locked in a drawer/closet where only the PI has access to. The data sheets are only accessible by the PI.

12.2.3 Analysis and archiving

The data will be analysed by excel. All the electronic data will be secured on a write-protected USB-stick. All the data sheets will be in two folders. Folder A includes the randomization-list, folder B the CRFs and questionnaires. The folders will be archived together with the USB-stick, for 10 years in a locked cabinet in the GLC.

12.2.4 Electronic and central data validation

For data validation purposes box plots will be calculated in order to check for data outliers. Frequency distributions and further descriptive analysis will be used to check for possible data errors.

12.3 Monitoring

The Sponsor monitors the study and will conduct spot checks.

12.4 Audits and Inspections

Not planned.

12.5 Confidentiality, Data Protection

Access to the source documents is permitted for purposes of monitoring and inspections. Otherwise the access to the dataset and the code list is only possible for authorized members of the study team. The study data are strictly used in a pseudonymized form. Publication of the study results will only be done with anonymized data.

12.6 Storage of biological material and related health data

Not applicable.

13. PUBLICATION AND DISSEMINATION POLICY

This study is a master thesis of the PI in cooperation with the Austrian Institute of Management (AIM) (FH Burgenland) and with Physiozentrum für Weiterbildung. At this moment it is not yet determined whether that study will be published or not.

14. FUNDING AND SUPPORT

14.1 Funding

No external funding.

14.2 Other Support

None.

15. INSURANCE

The study is classified in category A. The patients are insured by the physiotherapy practice's insurance (see attached insurance document). An additional insurance specifically for this study is not required.

16. REFERENCES

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die Mobiliar

Anhang: Betriebsversicherung GLC

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Hochdorf, 10.11.2018

neutrass residenz Versicherungen Vorsorge Finanzen
kontrolliert

Prämienrechnung 01.01.2019 - 31.12.2019

Betriebsversicherung
Police Nr. G-1271-6095
Versicherungsnehmer: Gesundheitspraxis Löwen Center AG, Zürichstrasse 9, 6004 Luzern

Vertragsanpassungen sind berücksichtigt bis 07.11.2018

Versicherungsprämie	CHF	4 243.85
Stempelabgabe	CHF	190.15
Ihre Prämienreduktion (Überschussfonds)	CHF	-424.40
Betrag zu unseren Gunsten, zahlbar bis 31.01.2019	**CHF**	**4 009.60**

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Empfangsschein / Récépissé / Ricevuta

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Versicherungsgesellschaft AG
3001 Bern

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Hochdorf, 11.11.2018

Indexierte Versicherungssummen ab 01.01.2019

Betriebsversicherung
Police Nr. G-1271-6095
Versicherungsnehmer: Gesundheitspraxis Löwen Center AG, Zürichstrasse 9, 6004 Luzern

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Diese Übersicht ist Bestandteil Ihrer Police und enthält die aktualisierten Versicherungssummen. Teilwerte und Standorte ohne Indexierung werden nicht aufgeführt. Diese unveränderten Versicherungssummen sind in Ihrer Police ersichtlich.

Inventar Peter de Regt und José van der Hoef, 6004 Luzern, Zürichstrasse 9

	Index bisher	Index neu	Summe/Wert	
Summe Bewegliche Sachen	104.82	105.99	CHF	1 101 100

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Hochdorf, 11.11.2018

Prämienübersicht ab 01.01.2019

Betriebsversicherung
Police Nr. G-1271-6095
Versicherungsnehmer: Gesundheitspraxis Löwen Center AG, Zürichstrasse 9, 6004 Luzern

Sachversicherung – Inventar Peter de Regt und José van der Hoef, 6004 Luzern, Zürichstrasse 9	CHF	1 966.15
Sachversicherung	CHF	529.55
Haftpflichtversicherung	CHF	1 748.15
Versicherungsprämie	**CHF**	**4 243.85**
Gesetzliche Abgaben (Stand: 01.01.2019)		
Stempelabgabe	CHF	211.25
Jahresprämie	**CHF**	**4 455.10**

Die Prämie ist jährlich zahlbar. Fälligkeit: 01.01.

In der Versicherungsprämie sind folgende Prämien gemäss Aufsichtsverordnung über die Elementarschadenversicherung enthalten: Feuer CHF 382.25, Elementar CHF 404.65.

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