On-line Neuromuscular Exercise and Education for Knee Osteoarthritis

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Statistical analysis plan

On-line Neuromuscular Exercise and Education for Knee Osteoarthritis

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Section 1: Administrative information

Title & trial registration

- 1a: **On-line Neuromuscular Exercise and Education for Knee Osteoarthritis**
  Due to enforced social distancing as a direct consequence of the COVID-19 pandemic, many on-site health care services are unavailable. This study seeks to investigate the comparative effectiveness of an alternative on-line delivery model of exercise and education compared to on-site delivery in patients with knee osteoarthritis.
- 1b: Trial registration: ClinicalTrials.gov Identifier: NCT04437134

Version

- 2: Version 2.0. Date: 28.04.2021

Protocol version

- 3: This document has been written based on the pre-registered trial protocol, available at ClinicalTrials.gov (see identifier in 1b).

Revisions

- 4a: Revision history

Version 1.0 (28.04.21) revised on 13.08.21

- 4b: Justification for revision

The original idea of on-line Good Life with osteoArthritis in Denmark (GLA:D®) was that it could be an additional delivery model to the existing on-site GLA:D®, providing individuals with knee osteoarthritis that were unable to come to the on-site GLA:D® or preferred the on-line version with an alternative, thereby potentially increasing the uptake of evidence-based care. Therefore, it was decided to change the framework of the analysis (see table below).

- 4c: Timing of revision

Protocol version	Updated SAP version no.	Section number changed	Reason	Date changed
	2.0	Section 2: Objectives and hypotheses. Section 6 (27): Statistical analyses.	After scientific discussion about the framework (superiority vs. non-inferiority), it was decided to revise to a non-inferiority design, since the success criteria of on-line GLA:D® lies in the similarity of effects with the traditional on-site version. We also revised the statistical analyses after consulting a medical statistician.	13.08.21

Roles and responsibility

- 5:

Principal investigator:

Pætur Mikal Holm, PT, PhD

Study chair:

Søren Thorgaard Skou, PT, Professor

Study co-chair

Ewa M. Roos, PT, Professor

Collaborator

Dorte Thalund Grønne, PT, Msc. (database manager)

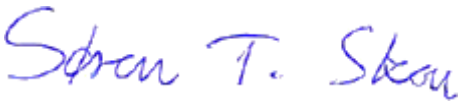
Signatures

- 6a: Principal investigator signature: 

  Date: 10.10.2021

- 6b: Database manager: 

  Date: 12.10.2021

- 6c: Study chair signature: 

  Date: 11.10.2021

- 6c: Study co-chair signature: 

  Date: 11.10.2021

Section 2: Introduction

Background

- 7: Synopsis of trial background and brief description of research question

Background

Due to the extraordinary events of the 2020 COVID-19 pandemic, finding alternative delivery-models of treatment has come to the forefront of public health services worldwide[1–3]. Consequently, on-line treatment is rapidly becoming an integral part of public health service[4,5]. For patients with knee

osteoarthritis (OA), where non-pharmacological and non-surgical treatment is considered first-line treatment[6], on-line delivered exercise has already shown promise and may be a viable treatment option, especially when traditional on-site exercise delivery models are unavailable[7,8]. However, further studies are needed to clarify the comparative effectiveness of on-line exercise and education when compared to on-site exercise and education programs. In Denmark, Good Life with Osteoarthritis in Denmark (GLA:D®) is the first line non-surgical treatment of patients with KOA, and Canada, Australia China, Switzerland, New Zealand, and Austria are currently implementing the treatment program[9,10]. The GLA:D® treatment consists of disease-specific education and neuromuscular exercise (NEMEX-TJR) to improve sensorimotor control and achieve compensatory functional stability[11,12]. It is currently unclear how an online delivery model of GLA:D® compares to traditional GLA:D® regarding treatment outcomes in patients with knee OA. Further insights will help understand the utility and scope of online delivery models of first line OA care.

This study aims to evaluate the effects of on-line delivery of the GLA:D® program compared to the same GLA:D® program delivered on-site in patients with knee OA.

Objectives

- 8:
    - **Objective 1 (primary)** is to investigate whether the effects on pain, function and quality of life (aggregate score) immediately after the treatment program differs between groups receiving 8 weeks of either on-line or on-site neuromuscular exercise (12 sessions) and education (2 sessions)
    - **Objective 2 (secondary)** is to investigate whether the effects on performance-based physical function and self-reported physical function, physical activity, pain, and quality of life differs between groups immediately after the treatment program
    - **Objective 3 (other)** is to investigate whether there are long-term (12 months) differences in participant satisfaction and perceived effect, continuation of exercise, usage of GLA:D self-management content and management of symptoms, intake of pain killers, sick leave, physical activity levels, and health-related quality of life between groups receiving 8 weeks of either on-line or on-site neuromuscular exercise (12 sessions) and education (2 sessions)

Hypotheses

Eight weeks of neuromuscular exercise (12 sessions) and education (2 sessions) delivered on-line is non-inferior to the same exercise and education program delivered on-site regarding the effects on pain, function and quality of life immediately after the treatment program compared to.

Section 3: Study methods

Trial design

- 9: Brief description of design

This is an observational study design, comparing two cohorts of knee OA patients receiving the same GLA:D® program (2 educational sessions, 12 exercise sessions) through different delivery models (on-line vs. on-site). Data from both cohorts is stored in the national GLA:D® registry.

The primary outcome is the summary score from the Knee Injury and Osteoarthritis Outcome Score, short version (KOOS 12). The primary follow-up is after completion of the exercise and education program (approx. three months). We will conduct a secondary one-year follow-up to assess the sustainability of treatment effects. Patients included into this study are adults, reporting knee OA symptoms. Both study groups (on-line and on-site GLA:D®) are comprised of patients with symptomatically verified knee OA.

Sample size

- 11: Full sample size calculation

This observational cohort will include all patients from the GLA:D® registry with baseline entry between May 2020 and May 2021. This period represents the 12 months in which on-line GLA:D® has been an optional delivery model in Region Zealand.

In this period, 89 patients had baseline entries in the GLA:D® registry in connection to enrolling for the on-line GLA:D® program. In the same period >5000 patients had baseline entries in the GLA:D® registry prior to enrolling for on-site GLA:D® program.

A one-sided power calculation for the primary outcome (KOOS) with common standard deviation of the change of KOOS set at 21, and sample sizes at 89 and a minimum of 5000, respectively; a power of 99.8% (non-inferiority limit equal to 15) is expected.

Framework

- 12. Description of hypothesis testing framework

This study investigates an alternative on-line delivery model of first-line care for knee OA patients, e.g. delivery of the same type of care, but with on-line supervision instead of on-site. The on-line delivery model provides an alternative way of receiving first-line OA care, increasing the uptake in those situations where on-site attendance is not possible or not wanted. Thus, the success threshold of the on-line delivery model lies in the similarity of effects with the traditional on-site delivery model. Therefore, all outcomes assessed for between-group effects are tested for non-inferiority of on-line GLA:D® compared to on-site GLA:D®.

Statistical interim analysis and stopping rules

- 13: Specification of planned interim analysis and/or stopping rules

There is no pre-planned interim analysis or stopping rules throughout the study.

Timing of outcome assessments

- 14: Details of timing of all analyses

The primary outcome is collected through self-report within three months after study enrollment. This follow-up extends to all secondary outcomes. Another follow-up one year after study enrollment includes the primary and secondary outcomes plus additional pre-specified outcomes.

Upon finishing the 8-week exercise and education program, all patients go through a physiotherapist led performance-based test of fast-paced walking ability and chair-stand ability along with recording of pain medication usage.

The self-reported follow-up within three months and after one year along with physiotherapist led performance-based tests and recordings is part of the mandatory data collection process in the national GLA:D® registry.

- 15: Study time points of all analyses

For complete overview of all follow-ups and timing, see table 1.

Statistical principles

Confidence intervals and p values

- 16: Level of statistical significance and confidence intervals

A 5% significance level (p=0.05) will be used as threshold for the null hypothesis of no differences between groups.

- 17: Adjustment for multiplicity

Since this study has one clearly defined primary outcome and all other outcomes serve as supportive outcomes, no adjustments for multiplicity are needed.

- 18: Confidence intervals

Open-ended 90%-confidence intervals will be used to establish non-inferiority.

Adherence and protocol deviations

- 19a: Definition of intervention adherence

High compliance to both on-site and on-line GLA:D® will be defined as attending both education sessions and ≥85% (minimum of 10 out of 12) of the exercise sessions.

Analysis population

- 20: Definition of analysis populations (FAS and PP)

The full analysis set (FAS) will consist of all participants with baseline data entry in the national GLA:D® registry between May 2020 and May 2021 with sensitivity analyses performed for those participants with a minimum of 1 attendance. The per protocol (PP) population is defined as those participants classified as having high compliance to the exercise and education program (see definition in 19a).

Trial population

Screening data

- 21: Reporting of screening data

The total number of eligible subjects throughout the recruitment period will be presented in a flow diagram along with total number of subjects screened for eligibility.

Eligibility

- 22: Summary of eligibility criteria

Patients included into this study are adults with knee OA symptoms. Both study groups (on-line and on-site GLA:D®) are comprised of patients with symptomatically verified knee OA.

On-line GLA:D®: Patients referred for assessment in secondary care due to knee OA symptoms.

On-site GLA:D®: Patients with knee OA symptoms referred to a physiotherapist either by their general practitioner, by an orthopedic surgeon, or by self-referral.

Inclusion Criteria:

- Knee OA symptoms resulting in contact with the health care system

Exclusion criteria:

- Another reason than OA for the problems; includes tumor or inflammatory joint disease
- Other symptoms that are more pronounced than the OA symptoms; i.e. chronic, generalized pain or fibromyalgia.
- Do not understand Danish

Recruitment and withdrawals

- 23 & 24: Information to be included in the CONSORT flow diagram
  - All participants with baseline data entry in the national GLA:D® registry between May 2020 and May 2021
  - The allocation of GLA:D® participants to on-site and on-line GLA:D®, respectively.
  - Number of participants completing 3-month follow-up for on-site and on-line GLA:D®, respectively.

Baseline patient characteristics

- 25a: List of baseline characteristics to be summarized

Table 1 will provide a descriptive summary of the following variables:

- Age, sex, BMI, educational level, co-morbidities, living alone, social status, sick leave, symptom duration, bilateral knee joint symptoms, hip pain, affected knees and hips (1-4), intake of pain killers, KOOS 12, 40m walk, 30 s chair-stand, KOOS 12 (subscale function), KOOS 12 (subscale pain), KOOS 12 (subscale quality of life), Health-related quality of life, Pain intensity (VAS 0-100), weekly physical activity and exercise, self-reported activity levels.

- 25b: Details on descriptive summary of baseline characteristics

Baseline characteristics will presented as frequencies or means with standard deviations (SD) as appropriate.

Section 6: Analysis

Outcome definitions

List and describe each primary and secondary outcomes including the following details:

- 26: Specification of outcomes and timing

Primary outcome

- The KOOS-12 Summary knee impact score

Summary score from the Knee injury and Osteoarthritis Outcome Score, short version (KOOS 12). The summary score is calculated as the average score from the KOOS 12 subscales pain, function and quality of life (QOL), ranging from zero (worst) to 100 (best)[13–15].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

Secondary outcomes

- Fast-paced walking ability

Fast-paced walking ability is recorded by the physiotherapists and evaluated using the 40-m fast-paced walk test[16].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months).

- Chair-stand ability

Chair-stand ability is recorded by the physiotherapists and evaluated using the 30-s chair-stand test[16].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months).

- Self-reported function

Patients self-report of function during daily life using the subscale function from the KOOS 12 questionnaire with scores ranging from zero (worst) to 100 (best)[13–15].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Self-reported pain

Patients self-report of pain using the subscale pain from the KOOS 12 questionnaire with scores ranging from zero (worst) to 100 (best)[13–15].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Self-reported quality of life

Patients self-report of quality of life using the subscale quality of life from the KOOS 12 questionnaire with scores ranging from zero (worst) to 100 (best)[13–15].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Pain intensity

Mean pain intensity during the last week in the most affected knee is evaluated on a 100 mm visual analogue scale (VAS) with terminal descriptors of 'no pain' (0 mm) and 'maximum pain' (100 mm)[17].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Physical activity and exercise

Patients self-report of time spent (frequency and duration) on structured physical activity and exercise.

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

<u>Other pre-specified outcomes</u>

- Patient satisfaction

Patients self-report of satisfaction with the GLA:D® program.

Time Frame: Primary follow-up point: Completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Continuation of exercise

Patients self-reporting if, how and where they have continued exercising.

Time Frame: Follow-up point: 12 months.

- Self-reported activity levels

Patients self-report their current activity levels using the University of California, Los Angeles (UCLA) activity scale, ranging from 1 (inactive, dependent on others) to 10 (regular participation in high-impact sports)[18].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Usage of what was learned during GLA:D®

Patients self-report of use of acquired skills and knowledge from the GLA:D® program.

Time Frame: Primary follow-up point: Completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Symptom management

Patients self-report of how they handle flare-ups in their knee OA symptoms.

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Intake of pain killers

Intake of painkillers is evaluated by the physiotherapist asking the patients about intake of any joint related medication. If taking painkillers, the patients are asked which type and whether or not they were taken because of their knee pain.

Time Frame: Primary follow-up: Change from baseline to completion of GLA:D® program (approx. three months).

- Sick leave

Patients self-report of sick leave due to knee symptoms.

Time Frame: Follow-up points: Baseline and 12 months.

- Health-related quality of life, index score

Patients self-report of their health situation using EuroQol, 5 dimensions, 5 levels (EQ-5D-5L) score (-0.624 to 1; worst to best)[19].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Health-related quality of life, visual analogue scale

Patients self-report of their health situation using the EuroQol visual analogue scale (EQ VAS), ranging from 0-100 (worst to best)[19].

Time Frame: Primary follow-up point: Change from baseline to completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Global perceived effect

Patients self-report of current knee condition compared to before participation in GLA:D®, scored on a 7-point likert scale (much worse to much better)[20].

Time Frame: Primary follow-up point: Completion of GLA:D® program (approx. three months). Secondary follow-up point: 12 months.

- Pain during exercise (only for on-line GLA:D®)

Patients self-report of pain during each exercise session, rated using a numeric pain rating scale (NPRS) 0-10, with zero representing no pain and 10 representing extreme pain[17].

Time Frame: Immediately prior to, and immediately after each exercise session.

Table 1|Timing of outcome measurements

Outcomes	**Baseline**	**After completing the GLA:D® program (approx. three months)**	**12 months after study enrollment**
The KOOS-12 Summary knee impact score	X	X	X
Fast-paced walking ability	X	X	
Chair-stand ability	X	X	
Self-reported function	X	X	X
Self-reported pain	X	X	X
Self-reported quality of life	X	X	X
Pain intensity	X	X	X
Physical activity and exercise	X	X	X
Patient satisfaction		X	X

Continuation of exercise			X
Self-reported activity levels	X	X	X
Usage of what was learned during GLA:D®		X	X
Symptom management	X	X	X
Intake of pain killers	X	X	X
Sick leave	X		X
Health-related quality of life, index score	X	X	X
Health-related quality of life, visual analogue scale	X	X	X
Global perceived effect		X	X

Analysis method

- 27: What analysis methods will be used

Between-group comparisons of the primary and secondary outcomes at completion of the GLA:D® program (approx. three months after starting GLA:D®) will be analyzed using a linear mixed model, with random intercepts for the patients and fixed effects of treatment (on-line/on-site), time (baseline to 3-month follow-up), and interaction between treatment and time (treatment x time) where time is treated as a factor variable. The analyses will be adjusted for potential confounders: Age, sex, BMI, comorbidities, number of affected knees and hips (score between 1 and 4), and education. Bootstrapping methods for inference will be implemented in case the residual errors or random-effect errors deviate from normal distribution. Normal distribution will be evaluated based on visual inspection of qq-plots. Between-group comparisons of all secondary outcomes will be analyzed using the same method as with the primary outcome.

Results will be reported as means and 90% confidence intervals (90% CI) for the non-inferiority comparison. Non-inferiority limits between the two treatment deliveries (on-site vs. on-line GLA:D®) are set according to previously defined thresholds for clinically relevant improvements in pain, function, and quality of life outcomes in knee OA: KOOS 12 and all KOOS 12 subscales (10 points)[13]; 40 m walk (0.095 m/s)[21]; 30 s chair-stand (two rises)[22]; VAS 0-100 (15 mm)[23]. To support the clinical interpretation of the results, we will also report a responder analysis of outcomes across the two treatment arms (on-site and

on-line GLA:D®). These will be defined and summarized as the number of participants across the two treatment arms achieving clinically relevant improvements from baseline to 3 month-follow-up (see definitions of clinically relevant improvements above). To guide the clinical interpretation of any differences between groups in absolute proportions of patients achieving clinically relevant improvements, we will use the following thresholds: 1) <20% between-group difference; *NO* difference between treatments. 2) 20-29% between-group difference; *LIKELY* difference between treatments. 3) ≥30% between-group difference; *DEFINITE* difference between treatments.

Outcomes listed as primary and secondary (with primary endpoints) will be reported in the primary report, while other outcomes will be reported in secondary reports.

Missing data

- 28: Handling of missing data

No imputation of data will take place, since linear mixed effects models handle missing data.

Additional analysis

- 29: Details of any additional analysis

Outcomes listed as 'other' and secondary endpoints (12 months after enrollment) will be reported in secondary reports.

Harms

- 30: Handling of adverse events

Potential adverse events (AE) will be defined as any contact with the health care system in relation to the index knee. The type of other contact with the health care system is derived by the physiotherapist after completion of the GLA:D® program (approx. three months). The number and description of the AE (type of contact with the health care system) will be summarized across both groups and reported in a table.

Statistical software

- 31: Details of statistical package used for the analysis

STATA 16 (or an updated version if applicable) (StataCorp, College Station, TX, USA).

Operating procedures

- 32: Data management

Data are stored and managed in the national GLA:D® registry (https://glaid.dk/index.html). The GLA:D® database manager will provide datasheets for the statistical analyses.

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