The Accuracy of Digital Assessment of Performance Trial; the ADAPT Study

Published: 17-11-2021
Last updated: 05-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON52000

Source
ToetsingOnline

Brief title
the ADAPT study

Condition

- Movement disorders (incl parkinsonism)
- Bronchial disorders (excl neoplasms)

Synonym
COPD, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Bedrijf,Verily Life Sciences

Intervention

Keyword: COPD, Digital biomarkers, Parkinson's disease, Walking tests

Outcome measures

Primary outcome

1) Difference between in-clinic 6MWT distance and free-living data based 6MWT distance estimate and 2) Difference between in-clinic 6MWT distance and Virtual 6MWT distance estimate

Secondary outcome

1) Difference between in-clinic TUG time and free-living data based TUG time estimate, 2) Difference between in-clinical TUG time and Virtual TUG time estimate and 3) Test-retest agreement across various estimates from each algorithm that is validated

Study description

Background summary

Physical functioning is an important determinant of quality of life and therefore a relevant issue in people with chronic conditions such as chronic obstructive pulmonary disease (COPD) and Parkinson*s disease (PD). Physical capacity and physical activity are distinct and relatively independent aspects of physical functioning. With the rise of innovative technology, both aspects have become measurable in the free-living environment of people with chronic conditions. However, so far, physical capacity and physical activity have mainly been assessed in in-clinic settings using standardized performance tests (i.e. Six-Minute Walk Test (6MWT)) and questionnaires (i.e. LASA Physical Activity Questionnaire), respectively. Here we will examine the validity of a digital solution to remotely measure physical capacity and physical activity in two groups of participants: participants with PD and participants with COPD.

Study objective

We aim to develop and validate algorithms to quantify and track physical

capacity and physical activity to be used as clinical trial endpoints for the development of pharmacological and non-pharmacological interventions for participants with COPD and PD. The algorithms will be developed from sensor data collected on wrist worn devices (Verily Study Watch and, for a subset of participants, the Fitbit Sense). There will be two contexts for sensor data collection 1) during the Virtual Walk Test, which is administered via application on a wrist worn device in the home setting, and 2) during the free-living context where participants simply wear the device(s) and the sensor data is passively recorded. In addition to the sensor data, each participant*s relevant clinical outcomes, patient-reported outcomes, general demographics and medical history information will also be collected. The resulting data will be used to develop and/or validate algorithms to estimate participant*s physical capacity as well as to quantify physical activity of the participant. By utilizing sensor data from wearable devices and their associated algorithms, we will be able to obtain frequent assessments of the participant*s functional physical capacity and granular measurements of physical activity. These will support an improved ability to measure a participant's physical functioning at baseline and during treatment, and has the potential to capture the treatment-related change from baseline. Ultimately we expect that this effort will contribute to more effective and efficient development of pharmacological and non-pharmacological interventions for people with COPD and PD.

Study design

We will perform a decentralized, prospective, observational study with a 15 week follow-up.

In Clinic Portion: Participants will come to their assigned local physiotherapy practice four times (once every five weeks) for in-clinic assessments of walking capacity, and will be instrumented with up to three sensor wearable devices (Verily Study Watch, Modus StepWatch 4, and the Fitbit Sense) during the walk tests. Participants will undergo 10 weeks of physiotherapy treatment as an intervention. No intervention is provided during the first five weeks of participation.

Remote Portion: Participants will be instructed to wear the Verily Study Watch for up to 23 hours per day for the entire study duration (15 weeks), to enable continuous free-living data collection, and will be asked to perform the Six-Minute Walk Test (6MWT) and Timed Up and Go test (TUG)) once a week using the Verily Study Watch. Verily Study Watch will send out notification to perform 6MWT and TUG and guide participants through the remote assessments. A subset of participants may also wear the Fitbit Sense concurrently with the Study Watch and will be asked to wear them for the first 5 weeks between first and second visits at minimum.

Study burden and risks

The burden of participating in this study consists of 4 visits to the local physiotherapy practice for in-clinic assessments of disease status and walking tests. These visits are scheduled in addition to the usual care physiotherapy assessments and therefore can be considered an additional burden. Every in-clinic visit will take approximately 120 minutes in total. In addition, participants are asked to wear the wearable device(s) continuously for 15 weeks and perform two walking tests once a week. The walking tests are guided and prompted by the Study Watch, making it easier to comply with these procedures. The Verily Study Watch is being used in another study in participants with PD and the participants showed excellent compliance3, therefore it is expected that this will be a realistic approach. For those who are willing to wear the optional device as well as the Verily Study Watch at home (minimum 50 people with COPD and 30 people with PD), simultaneous wear of the devices on each wrist, for at least the first five weeks of the study duration, will be an additional burden. It is expected this would be feasible based on prior studies where multiple devices were required to be worn for prolonged periods of time for the people with COPD4 and PD.5-7 In addition, this is not an obligatory part of the study, and participants can decline wearing multiple devices at the same time at home.

The main risks related to the safety of performing an unsupervised (submaximal) aerobic exercise test at home are related to falls and cardiovascular events. Falls may be more frequent in the PD population, while cardiovascular risk is higher in COPD because of (potentially undiagnosed) cardiovascular comorbidity. Risks associated with home measurement will be minimized by excluding participants that have fallen more than once in the last three months and by asking the treating physician (i.e. general practitioner, pulmonologist or neurologist) to assess a person*s ability to participate in this study. Finally, participants will receive 10 weeks of personalized physiotherapy, which they would also receive if they would not participate in this study.

Contacts

Public
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6524 GC
NL
Scientific
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6524 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

People with either COPD or Parkinson's disease (PD), able to walk independently and have a indication for physiotherapy

Exclusion criteria

Having fallen more than once within the last 3 months
Unstable heart condition

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2021
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Study Watch (smartwatch)
Registration:	No

Ethics review

Approved WMO Date:	17-11-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-01-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-05-2022

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL78292.091.21