ISRCTN15891080 https://doi.org/10.1186/ISRCTN15891080

Digital and paper-based DemTect for the detection of cognitive changes: How well do they agree and how good is the usability of the digital format?

Submission date
08/06/2023

Recruitment status
No longer recruiting

Registration date
09/06/2023

Overall study status
Completed

Last Edited
13/05/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cognitive impairment and its associated limitations have a major impact on the health of people worldwide and result in high healthcare costs. Patients recovering from serious illness, major surgery or infection often report temporary or long-lasting cognitive impairment. This also affects individuals recovering from a coronavirus infection. Approximately 20% of individuals with a confirmed coronavirus infection report long-lasting symptoms (or Long Covid) including cognitive difficulties such as forgetfulness, lack of focus, and impaired thinking. Cognitive assessments are critical in the management of individuals with Long Covid and play an important role in identifying cognitive impairment.

One of the most commonly used instruments to screen for cognitive impairment is DemTect. DemTect is usually administered by paper-and-pencil in a clinic by a physician or other health care professional. The company movos AG (https://www.movos.ch/) is currently developing a digital version (mobile app) of DemTect. The mobile app will allow individuals to perform DemTect by themselves without a health care professional. This may provide a more efficient and user-friendly screening method. The DemTect validation study will investigate how comparable and feasible the digital version of DemTect is compared to the paper-based version.

Who can participate?
A random selection of individuals from the general population of the Canton of Zurich, who participated in the Corona Immunitas Zurich seroprevalence studies (https://www.corona-immunitas.ch) and consented to be contacted for further research purposes, will be invited to participate in this study.

What does the study involve?
All participants will be invited for two study visits at the study center during which they will complete the digital and paper-based versions of DemTect. The order of the versions is random. At the first study visit, participants will be randomly divided into two groups:

• Group 1 fills out the paper-based version of DemTect at study visit 1 and the digital version at study visit 2 (three weeks after study visit 1).
• Group 2 will complete the digital version of DemTect at study visit 1 and the paper-based version at study visit 2 (three weeks after study visit 1).

Three weeks after the second visit, participants will be asked to complete the digital version of the DemTect on their own at home. They will also receive a questionnaire asking about the quality and their preferences regarding the two different versions.

What are the possible benefits and risks of participating?
The results of this study will help to develop a potentially more efficient and user-friendly screening method for detecting cognitive impairment. The risks of participating in this study are minimal.

Where is the study run from?
The study is run from the Epidemiology, Biostatistics and Prevention Institute (EBPI) at the University of Zurich, Switzerland.

When is the study starting and how long is it expected to run for?
May 2023 to January 2024

Who is funding the study?
Movos AG (Switzerland)

Who is the main contact?
Dr. Tala Ballouz, MD PhD MPH
tala.ballouz@uzh.ch

Contact information

Type(s)
Scientific

Contact name
Prof Milo A. Puhan

ORCID ID
https://orcid.org/0000-0003-4721-1879

Contact details
Epidemiology, Biostatistics and Prevention Institute (EBPI)
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001
+41 44 634 46 10
miloalan.puhan@uzh.ch

Type(s)
Scientific

Contact name
Dr Anja Frei

ORCID ID
https://orcid.org/0000-0002-7134-1000

Contact details
Epidemiology, Biostatistics and Prevention Institute (EBPI)
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001
+41 44 634 43 60
anja.frei@uzh.ch

Type(s)
Public

Contact name
Dr Tala Ballouz

ORCID ID
https://orcid.org/0000-0003-2334-8600

Contact details
Epidemiology, Biostatistics and Prevention Institute (EBPI)
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001
+41 44 634 35 48
tala.ballouz@uzh.ch

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Validation of self-administered digital DemTect for neurocognitive screening: a randomized crossover trial

Study objectives
The overall aim of this validation trial is to evaluate the agreement and usability of the digital (mobile-based) self-administered format of DemTect (SA-DemTect) for the detection of cognitive impairment compared with the traditional paper interviewer-administered format (IA-DemTect). We hypothesize that there is no difference between the scores of the two DemTect formats with regards to the total or domain scores, providing evidence of mutual exchangeability of the two formats.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/08/2023, Cantonal Ethics Committee Zurich (Stampfenbachstrasse 121, Zurich, CH-8090, Switzerland; +41 43 259 79 70; Info.KEK@kek.zh.ch), ref: 2023-01039

Approval pending, Ethics committee of the canton of Zurich, Switzerland (Kantonale Ethik-Kommission Zürich: Stampfenbachstrasse 121, CH-8090 Zurich, Switzerland; +41 43 259 79 70; Info.KEK@kek.zh.ch).

Study design
Single-centre randomized crossover trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Detection of cognitive changes (mild cognitive impairment and dementia) using DemTect - a validated neurocognitive screening instrument.

Interventions
Since this study is a crossover trial, all participants will receive both IA-DemTect and SA-DemTect and will act as their own controls. Eligible participants will be randomly assigned in a 1:1 allocation ratio using age stratified (<65 years and ≥65 years) block randomization to receive the two formats in a randomized order. The list of random numbers will be created in R software using the package blockrand.

According to the allocation sequence, participants will receive either :
- SA-DemTect first followed by IA-DemTect, or
- IA-DemTect followed by SA-DemTect.

These two assessments will be conducted during two study visits at the study center. SA-DemTect will be self-administered by participants on their mobile phones, and IA-DemTect will be conducted by trained research personnel. All participants will afterwards be asked to conduct the SA-DemTect assessment again at home. At the end of this third assessment, participants will receive an electronic questionnaire that assesses the usability of the app and their preference

with regards to the standard or digital version. Learning/practice effects are reduced by a three-week latency period between each of the assessments and by using three different versions of DemTect (A-C). For the administration of the IA format, we will use DemTect version B and for the administration of the SA format, we will use DemTect version A or C.

1. Paper-based interviewer-administered DemTect
The DemTect assessment contains five short and easy-to-administer tasks that assess the short and long-term verbal memory, working memory executive function, mental flexibility and language. The IA-DemTect is normally administered by healthcare professionals and requires little training. The total administration time is 8 to 10 minutes. For the purpose of this study, the assessment will be shown on a trial-specific web-based platform (developed by movos AG; accessed on a computer) rather than on paper. The administration of the IA-DemTect via the platform is identical to the traditional paper version and allows ease of data collection and minimizes error (e.g., score calculation errors).

2. Digital-based self-administered DemTect
The SA-DemTect will be available via an app that is compatible with both iOS and Android operated devices. Participants will be able to download and install the app with a personalized link and ID. Participants will only be able to access the app during the specific study visit in which they receive the SA-DemTect (app will be automatically deactivated after a single assessment completion). At the time of the third assessment (i.e., three weeks after the second visit), the app will be reactivated for another single use. The content and structure are identical to the standard IA-DemTect format with test instructions being shown directly on the phone. For tasks that usually require trained personnel to list words or numbers, the participant will be able to hear the instructions (numbers/words) directly through the app and will be asked to type or record them, depending on the individual task.

Intervention Type
Other

Primary outcome(s)
Degree to which the SA- and IA-DemTect scores and sub-scores agree with each other (assessed by the intraclass correlation coefficient). SA- and IA-DemTect scores are assessed at baseline and week three.

Key secondary outcome(s))
1. Agreement (assessed by kappa coefficients) of SA- and IA-DemTect in the classification of cognitive impairment (none, mild and significant cognitive impairment). SA- and IA-DemTect scores are assessed at baseline and week three.
2. Agreement of the two SA-DemTect assessments scores with each other (i.e., at-home versus clinical setting), as measured at baseline or week three (depending on the allocation sequence) and week six.
3. Differences in completion times of SA- and IA-DemTect assessments, measured at baseline and week three.
4. Usability of SA-DemTect evaluated at week six using participant questionnaires, and
5. Participant preferences with regards to the SA- and IA-DemTect evaluated at week six using participant questionnaires.

Completion date
20/01/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Fluent in German (reading and writing)
3. No documented neuropsychiatric disturbances influencing cognitive ability and ability to follow the study procedures
4. Have a mobile phone
5. Provided informed consent

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
153

Key exclusion criteria
All individuals not fulfilling the previously mentioned inclusion criteria will be excluded.

Date of first enrolment
09/08/2023

Date of final enrolment
08/11/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Zurich
Epidemiology, Biostatistics and Prevention Institute (EBPI)
Hirschengraben 84

Zurich
Switzerland
8001

Sponsor information

Organisation
University of Zurich

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Industry

Funder Name
movos AG

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant level data underlying the results reported in the publications will be made available at a later date directly from the authors or via an openly accessible repository.
tala.ballouz@uzh.ch

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes