Study into the feasibility and effectiveness of a personalised lifestyle intervention (LEEV!-intervention) in achieving long-term lifestyle improvement in adults with intellectual disabilities

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Primary objective:Can a personalised lifestyle intervention (LEEV!-intervention) support healthcare professionals in achieving effective and long-term lifestyle improvement (increased physical activity) for adults with ID to improve their lifestyle-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56799

Source
ToetsingOnline

Brief title
LEEV! Intervention study for adults with intellectual disabilities

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Lifestyle related health risks

Health condition

Kwetsbaarheid en sarcopenie

Research involving
Human

Sponsors and support

Primary sponsor: Hanzehogeschool
Source(s) of monetary or material Support: Regieorgaan SIA

Intervention

Keyword: Dietary behaviour, Intellectual disability, Lifestyle, Physical activity

Outcome measures

Primary outcome

The main study outcome is change in physical activity.

Secondary outcome

Study outcomes on an intrapersonal level

Anthropometry/body composition

• Height (cm from standing position, or using knee height)

• Body weight (kg) [calibrated weighing scale]

• Body Mass Index (kg/m2)

• Waist circumference (cm, standing up or in supine position)

• Hip circumference (cm)

• Waist to hip (ratio)

• Muscle mass (%, kg), fat mass (%, kg), fat free mass and total body water

(BIA)

Physical performance: ID-fit scan (mild-moderate ID) and test battery

(severe-profound ID)

• 30 seconds Chair stand and 5 times Chair stand

• Grip strength (kg)

• Static balance test

• Comfortable walking speed

• 6MWT

Questionnaires:

• Dietary quality

• ID-Frailty Index Short Form

• Anxiety, Depression And Mood Scale

• The Aberrant Behaviour Checklist

Study outcomes an interpersonal level

Questionnaires:

• ADSP-HENU

• ADSP-HEPA

• The Usefulness, Satisfaction, and Ease of Use Questionnaire

• The System Usability Scale

Study outcomes on an organisational level

Questionnaire:

• DIHASID

• MIDI-ID

Study description

Background summary

People with intellectual disabilities (ID) are living longer due to improvements in healthcare, but often not in good health. They face health issues like chronic disease, frailty, sarcopenia, sensory impairments, and limited mobility at a young age. Unhealthy habits like inactivity and poor diet choices contribute to these problems. Improving the lifestyle of people with ID is complex due to their physical and cognitive limitations, making existing interventions less suitable. Currently, there are no interventions for adults with ID that consider nutrition & physical activity, and intrapersonal, interpersonal, and location factors. We hypothesise that a personalised approach targeting all these aspects will increase physical activity and improve diet quality in adults with ID, and thereby an improvement of their health.

Study objective

Primary objective:
Can a personalised lifestyle intervention (LEEV!-intervention) support healthcare professionals in achieving effective and long-term lifestyle improvement (increased physical activity) for adults with ID to improve their lifestyle-related health?

Secondary objectives:
1. What is the feasibility of the LEEV!-intervention for adults with ID, the healthcare professionals, and the location/care organisation?

2. What is the effectiveness of the LEEV!-intervention for adults with ID on nutrition, physical activity levels, and lifestyle-related health outcomes, for the healthcare professional on their knowledge and skill acquisition, and for the location/care organisation on environment related to healthy living and efficiency of work processes?

Study design

We will conduct a feasibility study and a one-arm multiple baseline trial.

Intervention

Participants will follow a 9 month personalised lifestyle intervention targeting physical activity and diet quality. The intervention involves changes at an intrapersonal, interpersonal and location level

Study burden and risks

The possible benefits for participants include improvements in lifestyle and health through the personalised lifestyle intervention. This could lead to enhancements such as an improved nutritional status, better body composition, increased vitality, and an improved quality of life. The risks involved in participating in the study are minimal. Performed measurements within this study are similar to typical diagnostic activities during visits to a healthcare professional such as a physician, nutritionist, physiotherapist, lifestyle coach or behavioural specialist. Within the study, we strive to gather comprehensive information while minimising the burden on participants. In total we will perform five study visits. Three in the baseline period, one at the end of the intervention and one follow-up measurement after three months. The five study visits each last 45 minutes. Direct support professionals assist in fulfilling questionnaires with participants, which leads to a total time investment of 35 minutes (chapter 6, table 2). Over the intervention period of 9 months there will be biweekly coaching sessions, each lasting 30 minutes.Participation in an intervention can be experienced as burdensome, for example due to dietary restrictions and the time investment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Having an intellectual disability according to the international definition
• Eighteen years of age or older
• Having a lifestyle-related query
• Residing at or receiving support from one of the participating healthcare organisations
• Written informed consent from the participants themselves or a legal representative

Exclusion criteria

Participants will be excluded if they exhibit any of the following exclusion criteria shortly prior to entering the study:

- Severe mental or physical health issues that prevent the participant from taking part. The physicians, and behavioural scientists of the potential participant will evaluate whether the health condition of the potential participant requires exclusion from the study. In the end, the decision about in- or exclusion will be made in consultation between the physicians, behavioural scientist, representatives and principal researchers.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-06-2024
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-05-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	Het onderzoek zal worden geregistreerd op clinicaltrials.gov wanneer het onderzoek is goedgekeurd.
CCMO	NL85438.042.23