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Better ageing with personalized lifestyle support from a health coach using a digital app – a population-based intervention study in Germany

Submission date
26/03/2025

Recruitment status
Not yet recruiting

Registration date
12/06/2025

Overall study status
Ongoing

Last Edited
12/06/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims

Ageing is commonly associated with a decline in clinical and functional status and perceived well-being. This decline is associated with multi-morbidity, defined by the coexistence of two or more chronic disease conditions. Living with multi-morbidity impairs an individual's quality of life, health span and lifespan.

The study aims are to assess the effect of a personalised, digitally delivered lifestyle intervention on clinical status (waist circumference), functional status (hand grip strength) and perceived well-being (WHO 5 well-being index) after 1 year. The study will also evaluate the effect of the lifestyle intervention on the onset and severity of multimorbidity and death after 3 years.

The KORA Digital-Fit study is part of the STAGE project. STAGE is a European Research and Innovation project studying healthy ageing and multi-morbidity using a life-course approach (https://stage-healthyageing.eu).

Who can participate?

Men and women aged 50-79 years from the population-based KORA cohort (Cooperative Health Research in the Region of Augsburg) who are part of the baseline surveys will be invited to participate.

What does the study involve?

Participants will be assigned to the intervention or standard of care group according to personal preference and eligibility. The digital intervention will provide personalised digital health coaching aimed at managing and preventing chronic conditions like obesity, type 2 diabetes, and cardiovascular diseases. Both the intervention group and matched participants of the standard of care group will undergo an end-of-study assessment after 1 year, as well as a telephone interview after 3 years.

What are the possible benefits and risks of participating?
The intervention group will be informed about individual lifelong health. The findings are beneficial as they will be used to develop qualitative prevention concepts for the ageing population.

Where is the study run from?
KORA Study Center (Germany)

When is the study starting and how long is it expected to run for?
January 2024 to December 2029

Who is funding the study?
The KORA study was initiated and financed by the Helmholtz Zentrum München – German Research Center for Environmental Health, which is funded by the German Federal Ministry of Education and Research (BMBF) and by the State of Bavaria. Data collection in the KORA study is done in cooperation with the University Hospital of Augsburg. The KORA Digital-Fit study is part of the STAGE project. STAGE has received funding from the European Union's Horizon Europe Research and Innovation Programme under grant agreement n° 101137146. UK participants in Horizon Europe Project STAGE are supported by UKRI grant numbers 10112787 (Beta Technology), 10099041 (University of Bristol) and 10109957 (Imperial College London).

Who is the main contact?
Prof. Dr Annette Peters, annette.peters@helmholtz-munich.de

Study website
https://www.helmholtz-munich.de/en/epi/cohort/kora/kora-studienzentrum

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
24110

Study information

Scientific Title
Life-course informed, digitally supported, person-centred intervention study for the prevention of ageing with multi-morbidity in the population-based KORA study, Germany

Acronym
KORA Digital-Fit Study

Study objectives
The primary objective is to assess whether a personalized, digital delivered lifestyle intervention changes clinical status, functional status and perceived well-being after 1 year.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/03/2025, Ethics Committee of the Bavarian State Medical Association (Mühlbaurstraße 16, München, 81677, Germany; +49 (0)894147335; ethikkommission@blaek.de), ref: 24110

Study design
Single-center open-label two-armed parallel-group controlled study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stay healthy through ageing and prevention of multimorbidity

Interventions
A digitally delivered lifestyle intervention based on coaching regarding a healthy lifestyle with the overarching aim of ameliorating waist circumference, increasing muscle strength and perceived well-being over 1 year compared to standard of care.

Participants will be assigned to the intervention or standard of care group according to personal preference and eligibility. The digital intervention will provide personalised digital health coaching aimed at managing and preventing chronic conditions like obesity, type 2 diabetes and cardiovascular diseases. Both the intervention group and matched participants of the standard of care group will undergo an end-of-study assessment after 1 year, as well as a telephone interview after 3 years.

Intervention Type
Behavioural

Primary outcome measure
1. Waist circumference is measured using measuring tape at baseline and 1 year
2. Hand grip strength is measured using a hand dynamometer at baseline and 1 year
3. Well-being measured using the WHO-5 well-being index (self-report questionnaire) at baseline and 1 year

Secondary outcome measures
1. Multi-morbidity is measured by self-report at 3 years
2. Mortality is measured from record data at 3 years

Overall study start date
01/01/2024

Completion date

31/12/2029

Eligibility

Key inclusion criteria
1. Men and women aged 50-79 years from the KORA study
2. Informed consent for the planned study procedures

For the intervention arm:
1. Informed consent for the intervention study
2. Digital literacy and compatible personal device

Participant type(s)
Population

Age group
Mixed

Lower age limit
50 Years

Upper age limit
79 Years

Sex
Both

Target number of participants
3000

Key exclusion criteria
Participants who report a pre-existing severe comorbidity and/or a medical condition associated with a life expectancy of less than 1 year

Date of first enrolment
01/01/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Germany

Study participating centre
Kora Study Center
Beim Glaspalast 1

Augsburg
Germany
86153

Sponsor information

Organisation
Helmholtz Zentrum München

Sponsor details
Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)
Ingolstädter Landstraße 1
Neuherberg
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85764

Sponsor type
Research organisation

Website
https://www.helmholtz-munich.de

ROR
https://ror.org/00cfam450

Funder(s)

Funder type
Not defined

Funder Name
Deutsches Forschungszentrum für Gesundheit und Umwelt, Helmholtz Zentrum München

Alternative Name(s)
German Research Center for Environmental Health, Helmholtz Zentrum München

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Germany

Funder Name
European Union Horizon Europe Research and Innovation Programme under grant agreement n° 101137146

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be shared within the STAGE project. It will be available upon request from Helmholtz Munich in 2030.

IPD sharing plan summary
Available on request, Data sharing statement to be made available at a later date