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ELITE: Deep profiling and algorithmic polytherapy to map individual response in healthy aging

Submission date 27/09/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/09/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Aging affects several parts of health at the same time, including muscle function, immune function, cognition and metabolism. Clinical studies usually measure these areas only at a few clinic visits. ELITE tested whether two active healthy-aging treatment combinations could be studied together with frequent digital measurements collected between visits. The study also examined whether digital measurements could be linked to changes seen in clinical and laboratory assessments over time.

Who can participate?
The study enrolled community-dwelling adults aged 50 to 80 years without diabetes and with a body-mass index of at least 25 kg/m². Screening HbA1c was below 6.5%. Participants needed to be able to attend study visits and complete the required home digital assessments.

What does the study involve?
Participants were randomly assigned to one of two active treatment groups for about eight weeks. One group received metformin and semaglutide, and the other received metformin and empagliflozin. Both groups also received the investigational AgeBiotics products AB-01 and AB-02.

Participants completed frequent guided digital assessments at home using the ANI.AI platform. These included images of the tongue, eyes, face and wrist, a short survey, a voice recording and multispectral measurements of the tongue, face and wrist. Participants also attended scheduled clinic visits for clinical, physical, cognitive, laboratory and molecular assessments. The study used these repeated measurements to describe each participant's change over time and to compare digital response patterns with a Week 8 clinical measure covering muscular, immune and cognitive function. Randomized treatment-group assignment remained fixed during the pilot. Individual study products could be interrupted or discontinued when clinically indicated, but digital response states did not cause participants to be reassigned between the two randomized groups.

What are the possible benefits and risks of participating?
There was no guarantee of direct health benefit from participation. Participants received detailed clinical and laboratory assessments and physician-supervised study treatment. Possible risks included known side effects of the study medicines and investigational supplements, discomfort or bruising from blood sampling, and the time and inconvenience of completing repeated home assessments and clinic visits. Safety was monitored throughout the study, and treatment decisions remained under physician supervision.

Where is the study run from?
The study was conducted at Sheba Medical Center in Ramat Gan, Israel, using a hybrid clinic-home model.

When is the study starting and how long is it expected to run for?
The first participant was enrolled on 17 November 2025. Enrolment ended on 17 December 2025, and the final participant visit took place on 25 February 2026. Each participant took part in an approximately eight-week active intervention period, with optional digital observations collected after the required window.

Who is funding the study?
The study was funded by ANI BIOME PBC, with additional financial support from an award made by the XPRIZE Foundation. ANI BIOME PBC also provided the digital platform and investigational AgeBiotics products. The Sheba Fund for Health Services and Research served as the regulatory sponsor of record.

Who is the main contact?
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Additional identifiers

Israeli Ministry of Health MyTrial identifier
MOH_2026-07-21_016947

Study information

Scientific Title

Algorithmic Polytherapy in Healthy Aging (ELITE): a randomized Phase IIa pilot comparing two active multidomain intervention regimens using longitudinal multimodal phenotyping of individual muscular, immune and cognitive response

Acronym
ELITE

Study objectives
1. To assess change from baseline to Week 8 in the Muscular-Immune-Cognitive Composite (MIC-C), a multidomain clinical measure spanning muscular, immune and cognitive function
2. To assess safety and feasibility, including adverse-event incidence, severity and relatedness, study completion and overall protocol adherence
3. To characterize change in the muscular, immune and cognitive MIC-C subdomains and evaluate the relationship between change in a longitudinal multimodal digital health composite and change in MIC-C
4. To establish the operational measurement, provenance and clinical-governance framework required for future participant-specific response modeling and physician-authorized adaptive studies
5. To explore whether high-frequency digital response trajectories can identify Week 8 MIC-C responders and characterize longitudinal digital trajectory properties

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/09/2025, Sheba Helsinki Committee / Institutional Review Board (Derech Sheba 2, Ramat Gan, 5265601, Israel; +972 3 530 3810; Sigal.Gretz@sheba.health.gov.il), ref: 2361-25-SMC

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Healthy aging and multidomain functional health

Interventions
ELITE was a randomized, open-label, two-active-arm Phase IIa pilot conducted at Sheba Medical Center, Ramat Gan, Israel. Thirty-one adults aged 50-80 years without diabetes were randomized 1:1 after baseline procedures using a centralized secure web-based allocation system. The protocol specified permuted-block randomization stratified by sex and age decade (50-59, 60-69 and 70-80 years), with allocation concealed until assignment.

Arm A received metformin 425 mg orally once daily plus semaglutide 0.25 mg by subcutaneous injection once weekly for approximately eight weeks. Arm B received metformin 425 mg orally once daily plus empagliflozin 10 mg orally once daily for approximately eight weeks. Both arms also received the investigational AgeBiotics products AB-01 oral solution (three 19-mL sachets daily) and AB-02 (five capsules twice daily). Medication reminders and intake confirmation were incorporated into the digital workflow, and study/pharmacy records documented dispensing, treatment exposure, interruptions and discontinuations.

The study used a hybrid clinic-home measurement model. Participants completed frequent guided digital assessments through the ANI.AI platform, including tongue, left-eye, right-eye, face and wrist images, a structured micro-survey and a voice recording. Multispectral measurements of the tongue, face and wrist were also collected using a dedicated capture device. Digital sessions were timestamped and linked to source records. Scheduled clinic assessments provided body composition, cardiorespiratory, pulmonary, vascular/autonomic, muscular, mobility/frailty, cognitive, psychological, endocrine and clinical laboratory measurements, together with molecular sampling including metabolomic, proteomic, glycomic and metagenomic layers.

The protocol defined a Composite Response Score (CRS/ADAPT Score) derived from longitudinal digital biomarker data. Bayesian response probabilities supported prespecified KEEP, AUGMENT, SWITCH and STOPP response states for physician review. Randomized arm allocation remained fixed throughout the intervention period. CRS response states were generated and reviewed by physicians but did not trigger reassignment between randomized arms. Individual study products could be interrupted or discontinued for clinical or safety reasons under physician supervision.The Week 8 MIC-C served as the clinical anchor for the planned responder-validation analyses. Optional post-window digital capture was analysed separately from the required intervention-period measurements.

Intervention Type
Mixed

Primary outcome(s)
1. Physical strength, immune function, and brain health measured using Muscular-Immune-Cognitive Composite (MIC-C) score at baseline and week 8

Key secondary outcome(s)
1. Muscular and physical-function measured using muscular component of the MIC-C at baseline and week 8

2. Immune and biological assessments measured using immune domain score of the Muscular-Immune-Cognitive Composite (MIC-C) at baseline and week 8

3. Cognitive assessments measured using cognitive component of the MIC-C at baseline and week 8

4. Association between change in the longitudinal multimodal digital health composite and change in MIC-C measured using Spearman correlation at baseline to week 8

5. Incidence, severity and relatedness of adverse events measured using number and proportion of participants experiencing adverse events and serious adverse events, with events assessed for severity and relationship to study intervention according to the protocol-defined safety procedures at throughout the 8-week intervention period

6. Study completion rate measured using proportion of enrolled participants who completed the protocol-defined study follow-up through the week 8 assessment at week 8

7. Adherence to the assigned treatment regimen and scheduled app-based digital biomarker assessments measured using study medication records and ANI.AI digital logs at throughout the 8-week intervention period

Completion date
25/02/2026

Eligibility

Key inclusion criteria
1. Community-dwelling adults aged 50 to 80 years
2. Able to understand the study and provide written informed consent
3. Able to attend required study visits and complete home study procedures using a compatible digital device
4. Body-mass index (BMI) of at least 25 kg/m²
5. Screening glycated haemoglobin (HbA1c) below 6.5%, with no diagnosis of diabetes
6. Considered by the investigator to be able to comply with the study intervention and longitudinal digital monitoring requirements

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
50 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
31

Key exclusion criteria

1. Diabetes mellitus or current use of glucose-lowering medication outside the protocol-defined study treatment
2. Body-mass index below 25 kg/m²
3. Estimated glomerular filtration rate below 45 mL/min/1.73 m² or other clinically significant renal impairment affecting safety
4. Severe heart failure or recent major cardiovascular events
5. Active malignancy within the last 2 years, except successfully treated non-melanoma skin cancer or cervical carcinoma in situ
6. Chronic systemic corticosteroid use or other protocol-prohibited concomitant medication
7. Known hypersensitivity or contraindication to a study intervention
8. Cognitive, medical or other condition that, in the investigator's judgment, would make participation unsafe or prevent reliable completion of study procedures and daily digital assessments

Date of first enrolment
17/11/2025

Date of final enrolment
17/12/2025

Locations

Countries of recruitment
Israel

Study participating centre
Sheba Medical Center
Derech Sheba 2, Ramat Gan 5265601, Israel
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Sponsor information

Organisation
Sheba Medical Center

ROR
https://ror.org/020rzx487

Funder(s)

Funder type

Funder Name
Ani Biome PBC

Funder Name
XPRIZE

Alternative Name(s)
XPRIZE Foundation, X Prize Foundation Inc, X PRIZE Foundation, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available