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Comparing the effectiveness of an online interactive lifestyle intervention with general nutrition recommendations in rheumatoid arthritis and psoriatic arthritis patients with a low disease activity from a clinical, patient's as well as a societal point of view

Submission date
03/04/2023

Recruitment status
No longer recruiting

Registration date
13/06/2023

Overall study status
Ongoing

Last Edited
03/04/2025

Condition category
Musculoskeletal Diseases

[_] 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
The clinical outcomes of patients with inflammatory arthritis (IA), including rheumatoid arthritis and psoriatic arthritis, have improved enormously due to the further development of their management strategies. As a result over 80% of IA patients reach low disease activity. Despite reaching low disease activity, the disease still has a significant impact on patients' lives, which manifests itself in persistent fatigue, pain and morning stiffness. This residual disease activity is less in IA patients who are in remission. Unfortunately, remission occurs less often and is not always achievable with current treatments. In addition, IA patients still often want to taper their medication, despite the risk of a disease flare, because of (fear of) side effects. For the aforementioned IA patients, a lifestyle intervention program might be of added value. Lifestyle intervention programs can reduce inflammatory activity and subsequently might lessen disease impact and the risk of a flare.
Therefore, the aims of this study are:
1. To compare the clinical effectiveness between an online, interactive lifestyle intervention program and general nutrition recommendations in inflammatory arthritis patients with low disease activity, by looking at the proportional difference in remission and/or those who were able to taper their medication without having a disease flare after 12 months of follow-up.
2. To evaluate the cost-effectiveness of the online lifestyle intervention program versus general nutrition recommendations
3. To compare patient-relevant outcome domains; namely fatigue, pain, activity limitation, quality of life, sleep and worker productivity between the online lifestyle intervention program and general nutrition recommendations, but also between rheumatoid arthritis and psoriatic arthritis patients.

Who can participate?
Patients aged 18 years and over with rheumatoid arthritis or psoriatic arthritis

What does the study involve?
Patients are randomly allocated to an online, interactive lifestyle intervention program or to general nutrition recommendations. The lifestyle intervention program (called Leef! met reuma) consists of an intensive part of 6 months, followed by an aftercare program of 18 months. The online program focuses on four pillars: nutrition, exercise, relaxation and sleep. The diet that is prescribed is comparable to the Mediterranean diet, with an emphasis on unprocessed foods (especially vegetables). The general nutrition recommendations consist of information on the 'Schijf van Vijf, which is given during an online lecture of about 1 hour. There will be no follow-up on this lecture. Patients have a personal responsibility for the implementation of a healthier lifestyle after the given tools.

What are the possible benefits and risks of participating?
This study coincides well with patients' wishes and beliefs that they are in control and can self-treat their disease. To support their self-treatment lifestyle intervention programmes might be of added value. If successful, this study demonstrates that the interactive, online lifestyle intervention program can treat residual disease activity and leads to less disease burden, reflected by a higher remission and tapering without flare percentage, and lower costs (health care and societal).
Patients participate in an online, interactive lifestyle intervention program or receive general nutrition recommendations. Patients have a personal responsibility for the implementation into their own lives. In the researchers' opinion, the risks associated with participation are therefore low. Hypothetically, a food-drug interaction or an allergic food reaction could occur.
Although risks are low, there are still some drawbacks. Participation takes extra time. In order to keep this to a minimum, the study is as much as possible interwoven with daily practice. Study visits are planned as much as possible on the same day as the outpatient clinic visit.
Questionnaires can be filled out online at home. In the researchers' opinion, the knowledge they are expecting to gain from this study outweighs the study burden (number of study visits and time for filling out online questionnaires).

Where is the study run from?
Erasmus MC (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to May 2027

Who is funding the study?
Dutch Arthritis Society (Netherlands)

Who is the main contact?
Dr P.H.P. de Jong, p.h.p.dejong@erasmusmc.nl

Contact information

Type(s)
Principal Investigator

Contact name
Dr Pascal, H.P. De Jong

ORCID ID
http://orcid.org/0000-0001-6628-6222

Contact details
Dr. Molenwaterplein 40
Rotterdam
Netherlands
3015GD
+31 (0)6 28224368
p.h.p.dejong@erasmusmc.nl

Type(s)
Public

Contact name
Dr Pascal, H.P. De Jong

Contact details
Dr. Molenwaterplein 40
Rotterdam
Netherlands
3015GD
+31 (0)6 28224368
p.h.p.dejong@erasmusmc.nl

Type(s)
Scientific

Contact name
Dr Pascal, H.P. De Jong

Contact details
Dr. Molenwaterplein 40
Rotterdam
Netherlands
3015GD
+31 (0)6 28224368
p.h.p.dejong@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number
2022-001755-16

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

81013

Study information

Scientific Title
HEalthy Living in Inflammatory Arthritis (HELIA): a randomized controlled trial comparing efficacy between an interactive, online lifestyle intervention program and general nutrition recommendations

Acronym
HELIA

Study objectives
The primary outcome is the proportional difference in DAS28/DAPSA remission and/or those who were able to taper their medication without having a disease flare after 12 months of follow-up between inflammatory arthritis patients who followed the lifestyle intervention program and those who received general nutrition recommendations. The primary outcome for the cost-effectiveness analysis will be the incremental cost-effectiveness ratio (ICER), which is the ratio of the difference in costs to incremental benefits between the lifestyle intervention program and general nutrition recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2022, Medical Ethical Review Committee (Dr. Molewaterplein 40, 3015 GD, Rotterdam, Netherlands; +31 (0)10 7034428 or +31 (0)10 7033625; metc@erasmusmc.nl), ref: MEC-2022-0448

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Internet/virtual

Study type(s)
Other

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

Health condition(s) or problem(s) studied

Rheumatoid arthritis or psoriatic arthritis according to respectively 2010 criteria or CASPAR criteria (Symmetrical) joint inflammation with or without auto-antibodies (i.e. rheumatoid factor and/or anti-citrullinated protein antibodies) or psoriasis

Interventions

Patients have a personal responsibility for the implementation of the interactive online lifestyle program or general nutrition recommendations into their own lives. All food products are available at the local grocery store or butcher and participants have to buy them themselves.

Patients are randomized into an online, interactive lifestyle intervention program or general nutrition recommendations. To maintain group balance minimization randomization will be applied using CASTOR. The (prognostic) factors we are balancing are diagnosis (RA or PsA). Patients will be allocated to the online interactive lifestyle intervention program or general nutrition recommendations. Trained research nurses will examine patients and calculate the DAS or DAPSA depending on the diagnosis. The HELIA trial is an open-label randomized controlled trial and, therefore, there will be no blinding.

The lifestyle intervention program (called Leef! met reuma) consists of an intensive part of 6 months, followed by an aftercare program of 18 months. The online program focuses on four pillars: nutrition, exercise, relaxation and sleep. The diet that is prescribed is comparable to the Mediterranean diet, with an emphasis on unprocessed foods (especially vegetables). The general principles for each pillar are summarised below. All principles are further elaborated on during the live sessions (the why and how behind it), which are given via Teams or Zoom.

General principles of Leef! met reuma Pillar Principles:
Nutrition:
1. Eat unprocessed foods and vary in the foods you eat
2. Eat mostly plant-based
3. Pay attention to dietary quality and not solely energy content
4. Comparable to the Mediterranean diet.

Physical activity:
1. Strive to increase your heart rate with moderate-intensity physical activity for at least 15-30 minutes a day
2. Implement more physical activity during the day, all physical activity counts
3. Vary in the type of physical activity you do and find a type of physical activity that suits you and that you can enjoy

Relaxation:
1. Learn to notice when you are stressed and what causes you to be stressed
2. Find your personal way to implement relaxation
3. Control your breathing

Sleep:
1. Pay special attention to sleep quality and not only the amount of sleep
2. Develop your own personal, effective sleep hygiene

Participants are given tools to implement a healthier lifestyle and increase their health skills. They are invited to attend online meetings in groups (n = 25) and have 24/7 access to a secured online platform, which is accessible through the Voeding Leeft website. The lifestyle intervention is aimed at durable behaviour change (based on the I-Change model), and a coach is

involved to guide this. Overall, the guidance team is composed of a coach, dietician, program coordinator and experts with respect to sleep, relaxation and physical activity. The nutritional advice and diet advocated throughout the course are based on the guidelines of the Dutch Health Council and existing scientific literature; the diet is based on the Mediterranean diet.

Participants get access to a secured online platform, which is accessible through the Voeding Leeft website, and recipes for 30 days. Every month another pillar is central. During this month participants will get assignments to work on physical activity, relaxation and sleep every day for 10 days (with the option to extend to 28 days). For example, if stress reduction is the central pillar, then participants can follow short breathing exercises. If exercise is the central pillar of the month, then participants are encouraged to move or stretch more (e.g. short exercises /stretches on a chair behind a (work)desk).

The intervention extends over the course of 6 months (with the option to attend facultative follow-up meetings for up to 24 months). The program consists of various digital plenary and group meetings with dietary advice and online coaching, which are given via Teams or Zoom. On the online platform, which is accessible through the Voeding Leeft website, participants will also find more background information or they can ask questions (directed at the program coordinator, nutritionist, coach, or peers) or share their experiences, and track their progress. During the first 6 months, participants will be encouraged to attend all plenary and coaching sessions.

Plenary sessions include all participants (50 per group). During each session 1-2 pillars are centralized. The online sessions, which are given via Teams or Zoom, start with a presentation, and throughout the presentation participants can ask questions, after which the group is divided into several smaller coaching groups. In these groups the coach will explain how to implement specific changes in participants' lifestyles. During these coaching sessions individual obstacles or experiences/situations will also be discussed with the coach and peers. Finally, more in-depth information is given about the central pillar. One example is that participants will learn how to develop their own recipes according to the nutrition principles of the lifestyle program.

Also separate coaching sessions, will be organised. During these sessions the progress that participants have made will be discussed and evaluated. Within these sessions participants' obstacles are addressed and tips are given to help them stay motivated and keep the lifestyle behavioural changes they have made.

After the first 6 months, participants can participate in facultative sessions, which are given via Teams or Zoom, to stay motivated and foster the healthier habits they have learned throughout the course. These facultative sessions are similar to the coaching sessions, but will also include a recap of the knowledge about lifestyle that has been shared during the first 6 months of the program. A facultative session will be organised every nine weeks during this period. The total duration of these plenary, coaching and facultative sessions, during the entire follow-up, is respectively 16, 7 and 10 hours.

Finally, throughout the whole duration of the program, participants can access the Voeding Leeft online platform, which is accessible through the Voeding Leeft website, at any given moment of the day or week (24/7) to stimulate the implementation of healthier habits. All of the above is done to ensure the implementation of a more durable lifestyle behaviour change.

Noteworthy is the fact that there will be no information exchange between the treating rheumatologist and (the organisation of) the online, interactive lifestyle intervention program. However, for this trial Voeding Leeft will record whether participants attend the plenary and

coaching sessions and also track their activity on the online platform, which is accessible through the Voeding Leeft website.

General nutrition recommendations:
The general nutrition recommendations consist of information on the 'Schijf van Vijf, which is given during an (online) lecture of approximately 1 hour. There will be no follow-up on this lecture. The 'Schijf van Vijf' shows how much of what we eat overall should come from each food group to achieve a healthy, balanced diet. They recommend the following:
1. Eat at least 5 portions of a variety of fruit and vegetables a day
2. They should make up over a third of the food we eat each day
3. Choose from fresh, frozen, tinned, dried or juiced
4. Fruit juice and smoothies should be limited to no more than a combined total of 150 ml a day
5. Base meals on potatoes, bread, rice, pasta or other starchy carbohydrates
6. Starchy food should make up just over a third of the food we eat.
7. Choose higher fibre wholegrain varieties, such as wholewheat pasta and brown rice, or simply leave skins on potatoes
8. Have some dairy or dairy alternatives (i.e. soya drinks or yoghurts)
9. Eat some beans, pulses, fish, eggs, meat and other protein
10. Aim for at least two portions of fish every week, one of which should be oily, such as salmon or mackerel
11. Choose unsaturated oils and spreads, and eat in small amounts
12. Eat foods high in fat, salt and sugar less often and in small amounts
13. Drink plenty of fluids – the government recommends 6 to 8 cups or glasses a day
14. Water, lower-fat milk and lower-sugar or sugar-free drinks, including tea and coffee, all count

Intervention Type
Behavioural

Primary outcome measure
1. The proportional difference in DAS28/DAPSA remission and/or those who were able to taper their medication without having a disease flare after 12 months of follow-up between inflammatory arthritis patients who followed the lifestyle intervention program and those who received general nutrition recommendations. Disease activity in rheumatoid arthritis (RA) and psoriatic arthritis (PsA) patients is respectively measured with the DAS28 and DAPSA.
2. The incremental cost-effectiveness ratio (ICER), which is the ratio of the difference in costs to incremental benefits between the lifestyle intervention program and general nutrition recommendations. For the cost-effectiveness analysis the researchers will calculate the Quality Adjusted Life Years (QALYs) and total costs. Direct costs are the costs of treatment and medical consumption, whereas indirect costs are costs due to loss of productivity (i.e. presenteeism and absenteeism). Medication costs are calculated from doses reported in the patients' case records, valued according to the Dutch College of Health Insurance. Medical consumption, including duration of hospitalizations and admission diagnosis are recorded with the iMTA medical consumption questionnaire at baseline, 3 months, 6 months, 12 months and 24 months. The researchers will use the Dutch average length of stay by diagnosis if the duration of hospitalization is unknown. Indirect costs include not fully functioning, sick leave and reduction in work time. Worker productivity is measured with the Work Productivity and Activity Impairment (WPAI) questionnaire, which includes presentism and absenteeism at baseline, 3 months, 6 months, 12 months and 24 months.

Secondary outcome measures

1. Self-reported disease activity is measured with the RAPID-3 at baseline, 3 months, 6 months, 12 months and 24 months
2. General health is measured with a visual analogue scale at baseline, 3 months, 6 months, 12 months and 24 months
3. Pain is measured with a visual analogue scale at baseline, 3 months, 6 months, 12 months and 24 months
4. Morning stiffness is measured with a 10-point Likert scale at baseline, 3 months, 6 months, 12 months and 24 months
5. Fatigue is measured with a visual analogue scale at baseline, 3 months, 6 months, 12 months and 24 months
6. Functional ability is measured with the health assessment questionnaire (HAQ) at baseline, 3 months, 6 months, 12 months and 24 months
7. Quality of life is measured with the EQ-5D-5L at baseline, 3 months, 6 months, 12 months and 24 months
8. Quality of sleep is measured with the Medical Outcomes Study sleep scale (MOS-ss) at baseline, 3 months, 6 months, 12 months and 24 months
9. Perceived stress is measured with the Perceived Stress Scale at baseline, 3 months, 6 months, 12 months and 24 months
10. Physical activity is measured with the Dutch Standard for Healthy Exercise questionnaire at baseline, 3 months, 6 months, 12 months and 24 months
11. Diet compliance is measured with a self-developed questionnaire consisting of 17 questions at baseline, 3 months, 6 months, 12 months and 24 months

Overall study start date
01/01/2022

Completion date
21/05/2027

Eligibility

Key inclusion criteria
1. Diagnosed with rheumatoid arthritis (RA) or psoriatic arthritis (PsA), according to respectively the American College of Rheumatology (ACR)/European Alliance of Associations for Rheumatology (EULAR) 2010 criteria for RA and ClASsification for Psoriatic ARthritis (CASPAR) criteria
2. Low disease activity, defined as Disease Activity Score (DAS28)<3.5 and >2.6 or Disease Activity in PSoriatic Arthritis (DAPSA) <16 and >5
3. Stable disease-modifying antirheumatic drug (DMARD) dosage in the past 6 months
4. Age ≥18 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Unable to understand, speak and write in Dutch
2. Vegan diet/lifestyle or following a specific (medical) diet
3. Pregnant or nursing (lactating) women
4. History of bariatric surgery
5. Underlying metabolic, hematologic, renal, hepatic, pulmonary, neurologic, endocrine, cardiac, infectious or gastrointestinal conditions which in the opinion of the Investigator places the patient at unacceptable risk for participation in a lifestyle intervention program

Date of first enrolment
21/03/2023

Date of final enrolment
21/03/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus MC

Sponsor details
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD
+31 (0)10 70434602
r.dolhain@erasmusmc.nl

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Dutch Arthritis Society

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Netherlands

Results and Publications

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

Intention to publish date
21/05/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from P.H.P. de Jong (p.h.p.dejong@erasmusmc.nl) or Kim van Slingerland (k.vanslingerland@erasmusmc.nl). The type of data that will be shared is not currently known. The dates of availability aren't known yet. Consent from participants was required and obtained. All data is processed pseudo-anonymously. The Investigator will ensure that this trial is conducted in accordance with the principles of the Declaration of Helsinki.

IPD sharing plan summary
Available on request