ISRCTN74292348 https://doi.org/10.1186/ISRCTN74292348

Effects of GingerT3®, a specialized ginger extract, supplementation for mild to moderate joint pain

Submission date
30/04/2025

Recruitment status
No longer recruiting

Registration date
07/05/2025

Overall study status
Completed

Last Edited
30/07/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Over-the-counter (OTC) nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly taken to reduce inflammation and pain. Although NSAIDs are FDA-approved, chronic use may negatively affect the kidney, liver, and gastrointestinal mucosa and/or promote adverse cardiovascular events. For this reason, there has been interest in finding natural alternatives to NSAIDs that may reduce inflammation and/or perceptions of pain with fewer side effects. One possible nutritional alternative is Ginger extract like GingerT3™ (Specnova, LLC, Wilmington, DE), a high-potency ginger extract that comes from the rhizome of the ginger plant, Zingiber officinale Roscoe. It was designed to have high concentrations of specific classes of compounds to enhance joint support and mobility and reduce perceptions of pain. The purpose of this study is to examine the effects of ginger extract supplementation on markers of inflammation and joint health in individuals who experience mild joint pain in response to physical activity.

Who can participate?
Males and females between 40 and 75 years with a history of mild to severe joint and muscle pain.

What does the study involve?
Participants were matched by age, sex, and body mass and then randomly assigned to receive either 125 mg/day of a placebo or GingerT3® for 58 days. On days 0, 30, and 56 of supplementation, participants provided fasting blood samples, completed questionnaires, rated thigh pain in response to standardized pressure, and performed three sets of 10 squats or deep knee bends while carrying 30% of their body weight. Following each testing session, participants underwent a 2-day recovery period, after which the assessments were repeated.

What are the possible benefits and risks of participating?
Improvement of joint and muscle pain and mobility. The risk would be no experience of positive effects.

Where is the study run from?
Texas A&M University (USA)

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

Who is funding the study?
Specnova LLC (USA)

Who is the main contact?
Prof. Dr. Rick Kreider, rbkreider@tamu.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Rick Kreider

ORCID ID
https://orcid.org/0000-0002-3906-1658

Contact details
Department of Kinesiology & Sport Management
Texas A&M University TAMU 4253
College Station
United States of America
77843
+1 (0)979 458 1498
rbkreider@tamu.edu

Additional identifiers

Protocol serial number
IRB2022-1345

Study information

Scientific Title
Effects of ginger supplementation on markers of inflammation and functional capacity in individuals with mild to moderate joint pain

Acronym
GingerT3®

Study objectives
The aim of this study is to investigate how people who experience mild joint pain in response to physical activity perceive pain and inflammation markers after taking a supplement of this stronger ginger extract. Inflammation markers, functional capacity questionnaires, and muscle

pain ratings were the main results. Clinical blood markers of safety, reported side effects, over-the-counter analgesic use, joint flexibility, and quality of life were secondary outcomes. The researchers predicted that taking supplements containing this source of ginger would lower inflammation markers and pain perceptions because of its well-known anti-inflammatory qualities.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/04/2023, Texas A&M University's Institutional Review Board (TAMU 4253, College Station, 77843, United States of America; +1 (0)254 519 5741; irb@tamuct.edu), ref: IRB2022-1345

Primary study design
Interventional

Study design
Randomized placebo-controlled double-blind parallel-group and repeated-measures design

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Mild to severe joint and muscle pain

Interventions
Thirty men and women (average age 56.0±9.0 years; height 164.4±14 cm; weight 86.5±20.9 kg; BMI 31.0±7.5 kg/m²) with a history of mild to severe joint and muscle pain and inflammation participated in a randomized, double-blind, placebo-controlled, parallel-arm trial. On days 0, 30, and 56 of supplementation, participants provided fasting blood samples, completed questionnaires, rated thigh pain in response to standardized pressure, and performed three sets of 10 squats or deep knee bends while carrying 30% of their body weight. Each testing session was followed by a 2-day recovery period during which the assessments were repeated. Participants were matched by age, sex, and body mass and then randomly assigned (block randomization method) to receive either 125 mg/day of a placebo or GingerT3® for 58 days.

Intervention Type
Supplement

Primary outcome(s)
1. Muscle pain measured using the Algometer Graphic Pain Rating Scale (GPRS)
2. Functional capacity measured using three sets of 10 deep knee bends with dumbbells of approximately 30% of body mass
3. Markers of inflammation: creatine kinase, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), tumor necrosis factor-alpha (TNF-alpha), interleukin-6 (IL-6) using Clinical Pathology Laboratories (CPL)

Measured on days 0, 30, and 56 of supplementation and after 2 days of recovery following each testing session

Key secondary outcome(s)
1. Joint flexibility measured using the Sit and Reach Test and a goniometer to measure hip and knee range of motion
2. Quality of life measured using the SF-36 Quality of Life Questionnaire
3. Use of over-the-counter analgesics measured using the Over The Counter (OTC) Analgesic Medication Log
4. Clinical blood markers of safety measured using Chem-14 Panel, CBC, Lipid Panel using Clinical Pathology Laboratories (CPL)
5. Side effects reported using the Side-Effects Assessment Questionnaire

Measured on days 0, 30, and 56 of supplementation and after 2 days of recovery following each testing session

Completion date
16/12/2024

Eligibility

Key inclusion criteria
1. Males and females aged between 40 and 75 years
2. History of mild to severe joint and muscle pain with evidence of elevated inflammatory markers in the blood upon entry and/or history of physician-diagnosed osteoarthritis
3. Medically stable with no current uncontrolled cardiovascular, metabolic, or pulmonary disease. Participants will be able to participate if they are taking medications that would not affect study outcomes for non-related chronic diseases or disorders (e.g., to manage blood pressure, blood lipids, thyroid conditions, blood glucose, etc)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
33

Key exclusion criteria

1. No history of mild to severe joint and/or muscle pain.
2. History of uncontrolled cardiovascular, metabolic, or pulmonary disease
3. Pregnancy or a desire to become pregnant during the study
4. Current use of prescription COX-2 inhibitor medications (i.e., Celebrex (Pro)/celecoxib, Vioxx /rofecoxib, Bextra (Pro)/valdecoxib, Consensi (Pro) / amlodipine / celecoxib, Elyxyb (Pro) / celecoxib, indomethacin (Indocin)), corticosteroids (i.e., Alclometasone Dipropionate, Diprolene, Betamethasone Dipropionate, Qvar Redihaler, Beclomethasone Dipropionate, Pulmicort, Budesonide, Temovate, Clobetasol Propionate, Topicort, Desoximetasone, Decadron, Dexamethasone Acetate, Fludrocortisone Acetate, Fluticasone Propionate, Flonase Allergy Relief, Cortef, Hydrocortisone, Medrol, Methylprednisolone, Orapred, Prednisolone Sodium Phosphate, Prednisone, Kenalog, Triamcinolone, Dermotic, Cortone (cortisone), Nasarel (flunisolide), Asmanex (mometasone)), or disease-modifying antirheumatic drugs or DMARDS (i. e., Methotrexate / Rheumatrex, Trexall, Sulfasalazine / Azulfidine, Hydroxychloroquine / Plaquenil, Leflunomide / Arava, Azathioprine / Imuran) including Tumor necrosis factor (TNF) inhibitors (etanercept / Enbrel, infliximab / Remicade, adalimumab / Humira, certolizumab pegol / Cimzia, golimumab / Simponi), Interleukin-1 inhibitors (i.e., anakinra / Kineret), Interleukin-6 inhibitors (tocilizumab / Actermra, sarilumab / Kevzara), T-cell inhibitors (abatacept / Orencia), B-cell inhibitors (rituximab / Rituxan) or Janus kinase inhibitors or biosimilars (i.e., tofacitinib / Xeljanz, baricitinib / Olumiant, upadacitinib / Rinvoq).
5. A history in the prior month of bleeding disorders or current use of prescription blood thinner medications (e.g., Pradaxa (dabigatran), Eliquis (apixaban), Xarelto (rivaroxaban), Coumadin (warfarin), Plavix (clopidogrel), Effient (prasugrel), Brilinta (ticagrelor)). Low-dose use of OTC aspirin to promote heart health (e.g., < 325 mg/day) will be permitted. Individuals taking prescription medications to control chronic disease (e.g., glucose management, lipid lowering, anti-hypertensive, thyroid medications, etc.) that would not affect primary study outcomes (i.e., perceptions of muscle and joint pain) will also be permitted to participate in the study.
6. Inability to perform functional exercise tasks to be used in the study.

Date of first enrolment
06/04/2023

Date of final enrolment
08/08/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Exercise & Sport Nutrition Lab
Human Clinical Research Facility
Department of Kinesiology and Sports Management
Texas A&M University
TAMU 4253
College Station
United States of America
77843

Sponsor information

Organisation
SpecNova

Funder(s)

Funder type
Industry

Funder Name
SpecNova

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from the principal investigator Prof. Rick Kreider (rbkreider@tamu.edu). The raw data is available and can be shared upon written request, if the request is reasonable, as determined by the principal investigator.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/07/2025	30/07/2025	Yes	No