ISRCTN12004576 https://doi.org/10.1186/ISRCTN12004576

Therapeutic horticulture for well-being and stress in people with cancer

Submission date 09/11/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/11/2026	**Overall study status** Completed	
Last Edited 13/11/2026	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Ms Marta Bernile

Contact details
Department of Agricultural and Food Sciences (DISTAL), University of Bologna, Viale Fanin 44
Bologna
Italy
40127
+393891831163
marta.bernile2@unibo.it

Type(s)
Scientific, Public

Contact name
Prof Giuseppina Pennisi

Contact details
Department of Agricultural and Food Sciences (DISTAL), University of Bologna, Viale Fanin 44
Bologna
Italy
40127
+393933795999
giuseppina.pennisi@unibo.it

Additional identifiers

UK Research and Innovation (UKRI) number
10082340

Horizon Europe (GreenME project) number
101084198

Protocol Code
3354

Ethics committee trial registration number (Comitato Etico della Romagna, CET-CEROM)
3826

Study information

Scientific Title
Evaluation of the effects of a therapeutic horticulture program on well-being and stress levels in cancer patients: a non-pharmacological interventional pilot study

Study objectives
Primary objective:
To evaluate changes in the general well-being of cancer patients following participation in a therapeutic horticulture program at the IOR PRIME Center (Cesena, Italy)

Secondary objectives:
1. To evaluate changes in salivary cortisol levels, as an indirect measure of stress, following therapeutic horticulture activities
2. To evaluate the feasibility of therapeutic horticulture in an oncology setting as delivered at the PRIME Center
3. To explore the relationship between self-assessed well-being and salivary cortisol levels
4. To explore the measures in relation to the type of horticultural activity performed in each session

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/02/2025, Territorial Ethics Committee for the Romagna Wide Area (Comitato Etico Territoriale Area Vasta Romagna (CET-CEROM)) (c/o IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori", Via Piero Maroncelli 40/42, Meldola, 47014, Italy; +39 0543 739941; segreteriascientifica.ceav@irst.emr.it), ref: 849/2025

Primary study design
Interventional

Allocation
N/A: single arm study

Masking

Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Psychological well-being and stress in adults with cancer (any type and stage) receiving integrative oncology care

Interventions
Participants take part in a therapeutic horticulture program consisting of four weekly group sessions of two hours each over one month, delivered in the outdoor garden of the IOR PRIME Center and led by an agronomist trained in therapeutic horticulture in collaboration with a psychologist. Activities include sowing, transplanting, manual weeding, irrigation, harvesting, and plant propagation, with pre-planned alternatives (including indoor activities using natural materials) chosen according to weather conditions and participants' needs. Each session includes an introduction, a practical activity phase, and a closing/reflection moment. Participants are offered an optional experiential journal. The program is delivered in repeated cycles, and participants may join subsequent cycles. Assessments include the self-assessment of well-being and salivary cortisol sampling before and after each session, salivary cortisol reference samples collected at home on the three days before the program, and the Psychological General Well-Being Index (PGWBI), Connectedness to Nature Scale (CNS), and "Pollice Verde" questionnaire at baseline and after the program.

Intervention Type
Behavioural

Primary outcome(s)
1. Self-assessed general well-being measured using a single-item self-assessment on a 6-point facial scale (lower scores indicate better well-being) at immediately before and after each of the four weekly therapeutic horticulture sessions

2. Psychological general well-being measured using the Psychological General Well-Being Index (PGWBI), 22 items, Italian version, at baseline (within seven days before the first session) and at the final consultation after the four-session program

3. Connectedness to nature measured using the Connectedness to Nature Scale (CNS), Italian version, 5-point Likert scale, at baseline and at the final consultation after the four-session program

4. Gardening experience, attitudes and perceived benefits measured using the "Pollice Verde" questionnaire (15 items, non-validated) at baseline and at the final consultation after the four-session program

Key secondary outcome(s)
1. Salivary cortisol concentration (indirect measure of stress) measured using an electrochemiluminescence immunoassay at immediately before and after each of the four sessions; reference samples at 10:00 and 12:00 on each of the three days before the program

2. Feasibility of the therapeutic horticulture program, measured using the number of sessions attended relative to the number of sessions offered; recruitment, retention and completeness of data collection were also recorded, throughout the four-session program, and collected at the end of the study

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Diagnosis of cancer
3. Able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
7

Key exclusion criteria
Eastern Cooperative Oncology Group (ECOG) Performance Status ≥3

Date of first enrolment
02/04/2025

Date of final enrolment
03/10/2025

Locations

Countries of recruitment
Italy

Study participating centre
IOR PRIME Center
Via San Cristoforo 4200
Cesena (FC)
Italy
47522

Sponsor information

Organisation
University of Bologna

ROR
https://ror.org/01111rn36

Funder(s)

Funder type

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon, Horizonte Europa

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
UK Research and Innovation

Alternative Name(s)

UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymized individual participant data will be deposited in AMS Acta (https://amsacta.unibo.it/), the institutional open access repository of the University of Bologna, upon publication of the study results. Before deposit, data are available from the corresponding author (Giuseppina Pennisi, giuseppina.pennisi@unibo.it) upon reasonable request. Data sharing complies with participants' informed consent and applicable data protection regulations.

IPD sharing plan summary
Available on request, Stored in publicly available repository