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Support programme to improve wellbeing in family caregivers of children, adolescents and young adults receiving palliative or end-of-life care

Submission date 30/01/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/02/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 13/02/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Many children, adolescents and young adults live with serious non-oncologic conditions that limit or threaten their lives and require paediatric palliative care. Their families often face emotional, practical, and communication challenges that can affect their wellbeing. The aim of this study is to evaluate whether the PALLIAKID Intervention (a programme combining a structured needs assessment, support for advance care planning), with the support of a digital platform, can improve the wellbeing of family caregivers and enhance communication and decision-making within families and healthcare teams.

Who can participate?

1. Family caregivers of patients aged 0–19 years with a non-oncologic life-limiting or life-threatening condition
2. Patients aged 6–19 years receiving paediatric palliative care
3. Siblings aged 6–19 years
4. Healthcare professionals working in paediatric palliative care

What does the study involve?

Participants are randomly assigned to either:

1. Standard care, or
2. Standard care plus the PALLIAKID Intervention, which includes a structured needs assessment (HexCom-Ped) and advance care planning conversations (PALLIAKID IMPACT tool). The PALLIAKID Digital Platform will be used as a digital support to incorporate these two tools and track needs, symptoms, information and preferences.

Family caregivers, patients and siblings complete questionnaires at the start of the study, at 6 months, and at 12 months. Healthcare professionals also complete assessments of skills and communication practices. At the end of the study, some participants may take part in focus groups to share their experiences.

What are the possible benefits and risks of participating?
Potential benefits include better communication with healthcare professionals, clearer care planning, improved understanding of needs, and enhanced emotional support. Participants in the intervention arm may also find the digital platform helpful in organising information and sharing concerns.
Risks are minimal and relate mainly to the emotional nature of discussing sensitive topics such as illness, care needs and future planning. No experimental drugs or invasive procedures are involved.

Where is the study run from?
The study is coordinated by Fundació Sant Joan de Déu / Hospital Sant Joan de Déu (HSJD) in Barcelona, Spain, involving multiple European paediatric palliative care centres. The coordinating investigator is Dr Sergi Navarro.

When is the study starting and how long is it expected to run for?
April 2026 to December 2027

Who is funding the study?
The study is funded by the European Union's Horizon Europe Research and Innovation Programme, Grant Agreement 101137169

Who is the main contact?
Dr Sergi Navarro, sergi.navarro@sjd.es

Contact information

Type(s)
Principal investigator, Public

Contact name
Dr Sergi Navarro Villarrubí

ORCID ID
https://orcid.org/0000-0002-1009-8991

Contact details
Hospital Sant Joan de Déu (HSJD) (Part of Fundació Sant Joan de Déu – FSJD-CERCA). C/ Santa Rosa, 39–57, 4ª planta
Barcelona
Spain
08950
+34 (0)932 53 21 00
sergi.navarro@sjd.es

Type(s)
Scientific

Contact name
Dr Rita Malpique

ORCID ID

https://orcid.org/0000-0002-5282-6790

Contact details
Hospital Sant Joan de Déu (HSJD) (Part of Fundació Sant Joan de Déu – FSJD-CERCA). C/ Santa Rosa, 39–57, 4ª planta
Barcelona
Spain
08950
+34 (0)622 055 256
rita.malpique@sjd.es

Type(s)
Scientific

Contact name
Dr Lidia Bueno Sánchez

ORCID ID
https://orcid.org/0000-0002-0241-2717

Contact details
Calle Serpis, 29. Edificio Institutos de investigación
Valencia
Spain
46022
+34 (0)96 162 54 12
lidia.bueno@uv.es

Additional identifiers

Study information

Scientific Title
A multinational, randomized-controlled, parallel-group, open-label clinical study to evaluate the effectiveness of a comprehensive patient and family-centred intervention (PALLIAKID Intervention) to improve the wellbeing of family caregivers of children, adolescents and young adults in need of palliative and/or end-of-life care

Acronym
PALLIAKID

Study objectives
Primary objective:
Assess the effectiveness of the PALLIAKID Intervention in improving caregiver wellbeing.

Secondary objectives:
Assess broader psychosocial outcomes, communication and decision-making processes, professional competencies, cost-effectiveness, and feasibility.

Exploratory objectives:
Understand user experiences and contextual drivers of implementation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/11/2025, Ethics committee for research with medicines (CEIm) (Edifici Docent Sant Joan de Déu - c. Santa Rosa, 39-57, 3ª planta, Barcelona, 08950, Spain; +34 (0)93 600 97 51; info@fsjd.org), ref: PIC-169-25

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Palliative care needs in children, adolescents and young adults, and caregiver burden and wellbeing among their family caregivers

Interventions
The study consists of two arms: an intervention arm receiving the PALLIAKID Intervention in addition to standard paediatric palliative care, and a control arm receiving standard care only. Participants are randomised 1:1 using simple randomisation with stratification by patient gender and age (<12/≥12 years); randomisation is generated through the IDAS system and implemented in the electronic case report form (eCRF).

Participants in this arm receive usual paediatric palliative care plus a multicomponent intervention comprising:
HexCom-Ped needs assessment tool

A structured, multidimensional needs assessment conducted by trained professionals to evaluate clinical, psychosocial, emotional, spiritual and family needs. Assessments may occur more than once depending on patient/family complexity and evolving needs.

PALLIAKID IMPACT Advance Care Planning tool:
A culturally adapted and digitalised ACP resource guiding structured discussions on values, goals of care, preferences, and planning of future scenarios. It supports preparation, documentation, and updating of individualized care plans.
The PALLIAKID Digital Platform will provide a digital support environment providing tailored interfaces for caregivers, patients, siblings and professionals. It includes ACP resources, needs assessment tools, a patient journey dashboard, symptom tracking, milestone planning, recommendations, and reminders. Participants are expected to engage with the platform 10–50 minutes per week, depending on their needs and preferences.

Schedule and duration:
Baseline visit (0 months): consent, randomisation, baseline assessments, initial HexCom-Ped assessment, introduction to the digital platform.
6-month visit: follow-up questionnaires and assessment of the primary endpoint.
12-month visit: final questionnaires, HexCom-Ped assessment, and participation in qualitative feedback (focus groups).
The intervention period lasts 12 months.

Control arm: standard care
Participants in the control arm receive the standard paediatric palliative care delivered at their clinical site, without access to the PALLIAKID Intervention components. Standard care includes routine follow-up, symptom management and psychosocial support as normally provided by the PPC team.

Control participants complete:
1. Baseline assessments
2. A 6-month follow-up
3. A 12-month final evaluation including one HexCom-Ped needs assessment for comparative purposes

No placebo is used

Randomisation:
Randomisation follows a simple randomisation scheme with a fixed 1:1 allocation ratio, stratified by gender and age group. Minimisation ensures balanced allocation across clinical sites. Randomisation numbers are generated by the IDAS system and maintained locally by the principal investigator or delegated research staff.

Intervention Type
Behavioural

Primary outcome(s)
1. Caregiver wellbeing measured using the Family Appraisal of Caregiving Questionnaire – Palliative Care (FACQ-PC) at at baseline and 6 months

Key secondary outcome(s)
1. Quality of life in family caregivers measured using the Quality of Life in LifeThreatening Illness – Family Carer Version (QOLLTI-F) at at baseline, 6 months and 12 months

2. Quality of communication in family caregivers measured using the Quality of Communication (QOC) questionnaire at at baseline, 6 months and 12 months

3. Health-related quality of life in patients (children/AYAs) measured using the Disabkids questionnaire at at baseline, 6 months and 12 months

4. Health-related quality of life in patients (children/AYAs) measured using the Disabkids questionnaire at at baseline, 6 months and 12 months

5. Physical and emotional symptom burden in patients measured using the PediQuest Memorial Symptom Assessment Scale (PQ-MSAS) at at baseline, 6 months and 12 months

6. Needs in paediatric palliative care (patients) measured using the Pediatric Palliative Care Questionnaire (PPCQ) at at baseline, 6 months and 12 months

7. Communication skills and self-efficacy in healthcare professionals measured using the Pediatric Provider Communication Skills Assessment Scale and the Pediatric Palliative Care Questionnaire (PPCQ) at at baseline, 6 months and 12 months

8. Psychological adjustment in siblings measured using the Negative Adjustment Scale (NAS) at at baseline, 6 months and 12 months

9. Usability of the digital platform measured using the System Usability Scale (SUS) at at 12 months

10. Cost-effectiveness of the intervention measured using the EQ-5D-3L or EQ-5D-5L at baseline and 6 months to calculate QALYs, and healthcare resource use measured using hospital records of emergency room admissions and unplanned hospitalisations cumulatively at over 6 months

11. Engagement and adherence to the intervention measured using screening logs, usage metrics of the digital platform and participation records collected continuously at during the intervention period (12 months)

12. Feasibility and acceptability of the intervention measured using qualitatively using focus groups at at 12 months

Completion date
01/12/2027

Eligibility

Key inclusion criteria
Inclusion criteria for family caregivers:
1. Family caregivers of a patient (aged ≥0 years and <20 years at study start, of any gender) affected by a non-oncologic life-limiting or life-threatening disease, and referred to a paediatric palliative care team of the site
2. Ability to speak, read and understand in either of the official languages of the country or English
3. With access to an internet connection and mobile device (e.g., smartphone or tablet)
4. Signed informed consent form. The consent from parent(s)/guardian(s) will be obtained following the rules of the specific countries

Inclusion criteria for patients:
1. Patients aged ≥6 years and <20 years at study start, of any gender

2. Affected by a non-oncologic life limiting or life-threatening disease
3. Currently receiving care by/referred to a paediatric palliative care team at one of the participating clinical sites
4. Appropriate communication skills in either of the official languages of the country or English
5. With access to an internet connection and mobile device (e.g., smartphone or tablet)
6. Signed informed consent form for patients older than 18 years old and signed informed assent for patients, when required, according to the rules of the specific countries

Inclusion criteria for siblings:
1. Children and Adolescents and Young Adults (AYAs) aged ≥6 years and <20 years at study start, of any gender
2. Appropriate communication skills in either of the official languages of the country or English
3. With access to an internet connection and mobile device (e.g., smartphone or tablet)
4 .Signed informed consent for participants older than 18 years old and signed informed assent for participants younger than 18 years old, when required, according to the rules of the specific countries

Inclusion criteria for healthcare professionals:
Any health professional being part of the paediatric palliative care team of the participant site working with patients (aged ≥0 years and <20 years at study start, of any gender) affected by a nononcologic life-limiting or life-threatening disease.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 Years

Upper age limit
19 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Exclusion criteria for patients, siblings, and family caregivers:
Anyone who is not able to participate in the study according to the clinical judgement of the site chief investigator or any other authorised person of the research team if deemed that participation could be harmful. This judgement has to be documented in writing for each child /parent not being enrolled.

Date of first enrolment
01/04/2026

Date of final enrolment

31/12/2026

Locations

Countries of recruitment
Denmark

Finland

Italy

Latvia

Spain

Sponsor information

Organisation
Fundació Privada per a la Recerca i la Docència Sant Joan de Déu (FSJD-CERCA)

Funder(s)

Funder type

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available