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The effect of the “Joining Uncertainty Management & Meaning Making Program” to promote patient-centered care in hematopoietic stem cell transplantation

Submission date
23/02/2025

Recruitment status
No longer recruiting

Registration date
20/04/2025

Overall study status
Ongoing

Last Edited
27/02/2025

Condition category
Other

[_] 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 study team have developed and implemented an uncertainty-management program based on meaning-making and evaluated the effect of the program on uncertainty, personal growth, healthcare empowerment, and self-efficacy.

Who can participate?
Patients undergoing hematopoietic stem cell transplantation aged between 18 and 69 years old

What does the study involve?
The intervention program included seven sessions. In the first session, participants learned how to use a smartphone app to check their blood count and scan QR codes. They were given help to install the app and shown how to use it. Throughout the program, they received ongoing education and support through phone calls or face-to-face meetings. The team also checked if participants were using the educational materials and provided extra help if needed. Regular phone calls were made to answer any questions and support them through the transplant process.

What are the possible benefits and risks of participating?
This study is expected to contribute to the literature by showing that interacting with medical professionals and receiving information and education at the patient’s level of understanding and treatment condition effectively decreases uncertainty and helps them find meaning in a difficult journey.

This study is not an intervention involving medication or treatment, but rather counseling and education with patients, so participation is not expected to cause harm. However, the consent form states that if the patient withdraws consent or wishes to discontinue it, he or she may express his/her intention.

Where is the study run from?
The study is hospital-based at the Asan Medical Center, South Korea, but interaction will occur at any time when participants need help.

When is the study starting and how long is it expected to run for?
January 2019 to December 2025

Who is funding the study?
Asan Medical Center, South Korea

Who is the main contact?
Mrs Young-shin Lee, lysinkorea@amc.seoul.kr, lysinkorea@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20191128

Study information

Scientific Title
Development and evaluation of joining uncertainty management & meaning making program for hematopoietic stem cell transplantation patients

Study objectives
Hypothesis 1: The level of uncertainty in the experimental group, who participated in the uncertainty-management program based on meaning-making, will become distinctively different over time from that of the control group.
Hypothesis 2: Compared to the control group, the level of personal growth will be higher in the experimental group, who participated in the uncertainty-management program based on meaning-making.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/11/2019, IRB committee, Asan Medical Center (88, Olympic-RO 43-GIL, Songpa-Gu, Seoul, 05505, Korea, South; +82-2-3010-7166; irb@amc.seoul.kr), ref: S2019-2341-0002

Study design
Nonequivalent control group non-synchronized quasi-experimental design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Internet/virtual, Telephone

Study type(s)
Safety, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Meaning-making to an intervention program for managing the uncertainty of patients undergoing HSCT

Interventions
Based on previous study findings, an intervention program was constructed comprising seven sessions. Session 1 took about 30 minutes. To begin the JUM3P, participants had to understand how to check their blood count using a smartphone app and how to scan a QR code. Thus, about 20 minutes were spent helping install the program and checking to see if patients could use the tool on their own. In addition, a demonstration was given when patients had difficulty understanding. From then on, patients were continuously educated and provided consultation through phone calls or face-to-face interviews regarding their areas of concern. It was also checked whether they had looked at the educational content using the QR codes. Those who had forgotten how to use the QR codes were re-educated and given verbal additional information in an orderly fashion. The network with the patients was maintained by visiting with them via phone calls when it was expected they would have questions or a hard time coping with the transplant process.

Intervention Type
Behavioural

Primary outcome measure
The following primary outcome measures are assessed at T1 (baseline at enrollment), T2 (before conditioning regimen for HSCT), and T3 (one week after discharge):
1. Uncertainty measured using the Mishel-Uncertainty of Illness Scale (MUIS)
2. Personal growth measured using the Growth through Uncertainty Scale (GTUS)
3. Healthcare competency measured using the Health Care Empowerment Inventory (HCEI)
4. Self-efficacy measured using the General Self-Efficacy Scale (GSE)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2019

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. In-patients undergoing allogeneic HSCT for the first time after being diagnosed with a blood disorder
2. In-patients and out-patients preparing for allogeneic HSCT
3. Men or women between the ages of 18 and 69 years

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
54

Total final enrolment
35

Key exclusion criteria
1. A person with a psychiatric history or currently receiving treatment for a psychiatric disorder
2. A person undergoing emergency HSCT
3. A person needing a caregiver’s help due to a weakened physical condition at the time of recruiting the research participants

Date of first enrolment
28/11/2019

Date of final enrolment
02/11/2021

Locations

Countries of recruitment
Korea, South

Study participating centre
Asan Medical Center
88, Olympic-RO 43-GIL, Songpa-Gu
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Sponsor information

Organisation
Asan Medical Center

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://eng.amc.seoul.kr/gb/lang/specialities/departments.do?hpCd=D012

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Asan Medical Center

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Young-shin Lee, lysinkorea@amc.seoul.kr, lysinkorea@gmail.com. Participants were notified that their information would be kept confidential and would not be used for any other purpose except for the research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/02/2025	No	Yes