

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/02/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Safety, Efficacy

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(s)

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)

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

69 years

Sex

All

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

Seoul

Korea, South

05505

Sponsor information

Organisation

Asan Medical Center

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Asan Medical Center

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes