Magnet4Europe - Improving mental health and wellbeing in the health care workplace

| Submission date | Recruitment status No longer recruiting | [X] Prospectively registered | | |
|-------------------|---|------------------------------|--|--|
| 31/03/2020 | | [X] Protocol | | |
| Registration date | Overall study status Completed | Statistical analysis plan | | |
| 10/04/2020 | | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 04/11/2025 | Other | | | |

Plain English summary of protocol

Background and study aims

Mental health and wellbeing are among the highest priorities of the public health agenda in the European Union (EU). A large-scale European study of hospital work conditions and associated nurse and patient outcomes revealed high rates of job dissatisfaction and burnout, with burnout rates varying between 10% and 78%. Physician burnout rates ranging from 25% to 60% have been reported, varying across organizations and medical specialties. Magnet4Europe aims to redesign clinical environments in sixty hospitals in five European countries (Belgium, United Kingdom, Germany, Ireland, and Sweden) to promote the mental health and wellbeing of health professionals. Magnet4Europe will implement an evidence-based intervention based on the successful Magnet Recognition Program®, a voluntary hospital designation for nursing care excellence by the American Nurses Credentialing Center. Countless studies have shown that Magnet-recognized hospitals have lower health professional burnout and safer patient care suggesting that the Magnet journey is an intervention that results in positive changes Magnet4Europe seeks to achieve.

Who can participate?

Hospitals with more than 150 beds focused on acute care for adults.

Health professionals working at these hospitals who have direct patient contact and work on inpatient units.

What does the study involve?

In the Magnet4Europe study we will be studying and measuring various items in relation work environment (work relations, job satisfaction, perception of the quality of care and workload) and mental health of health professionals working in acute care hospitals. These items and topics will be measured using standardised and validated questionnaires. The Magnet4Europe study will run for four years and during this period you will be annually invited to take part in a survey. When you decide to take part in the Magnet4Europe study and engage in the survey, you will be asked to register yourself on the Meplis Care Monitor. The Care Monitor will provide access to the survey. You will receive an activation URL, allowing you to register yourself on the Care Monitor. You will receive instructions through the application on how to get started with the questionnaire. You will then be asked a number of questions about your perception of your working environment: the relationship with the doctors, the workload and staffing of the ward,

any intention (if any) to leave the profession, patient safety, etc. The questionnaire takes approx. 20 minutes to complete; it should be completed within two weeks of receiving the invitation. You will receive three more invitations after this (i.e. one invitation every following year).

What are the possible benefits and risks of participating?

Benefits: You have no benefit from participating in the Magnet4Europe study and will not be compensated for your participation. However, we hope that your participation in the study will help us to gain more insight on how you perceive hospital care and the demands that are placed on clinical staff. By doing so, you can help to improve the working environment and safety of patient care.

Risks: There are no disadvantages associated with participation. Neither the research team nor the hospital will know whether you have participated in the study or not. A possible refusal to participate in the study will have no adverse effect on your employment at this hospital; nor will your answers have any effect on your participation.

Where is the study run from?

University Hospitals Leuven (Belgium) and recruiting in Belgium, United Kingdom, Sweden, Ireland, Norway, and Germany.

When is the study starting and how long is it expected to run for? September 2020 to June 2024

Who is funding the study? European Commission Horizon 2020

Who is the main contact?

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Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

274132

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

848031, IRAS 274132

Study information

Scientific Title

A workplace organizational intervention to improve hospital nurses' and physicians' mental health: protocol for the Magnet4Europe wait-list cluster randomized controlled trial

Acronym

Magnet4Europe

Study objectives

The objective is the implementation of the Magnet® Model of organizational redesign in acute care hospitals in Europe using a multi-component implementation strategy, reduces burnout rate and mental health morbidity among physicians and nurses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Belgium: Approved 02/10/2020, Ethics Committee Research UZ/KU Leuven (Herestraat 49, 3000 Leuven, Belgium; +32 (0)16 34 86 00; ec@uzleuven.be), ref: S64213

Sweden: Approved 23/09/2020, Swedish Ethical Review Authority (Postal address Box 2110, SE-750 02 Uppsala, Sweden; registrator@etikprovning.se), ref: 2020-03842

UK: Approved 01/09/2020, University of Southampton Ethics and Research Governance (ERGO, Head of Research Integrity and Governance, Research and Innovation Services, Southampton, SO17 1BJ, UK; +44 (0)2380595058; rgoinfo@soton.ac.uk), ref: 52986

UK: Approved 30/10/2020, NHS Health Research Authority (2 Redman Place, Stratford, London, E20 1JQ, UK; tel: not provided; approvals@hra.nhs.uk), ref: 274132

Ireland: Approved 12/08/2020, Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC; University College Cork, Lancaster Hall, 6 Little Hanover Street Cork, Ireland; +353 (0)21 4901901; crec@ucc.ie), ref: ECM 4 (s) 11/08/2020

Germany: Approved 30/10/2020, Ethikkommission Charité – Universitätsmedizin Berlin (Ethikausschuss am Campus Charité Mitte, Vorsitzender Prof. Dr. R. Morgenstern, Charité Universitätsmedizin Berlin, Ethikkommission der Charité, z.Hd. Dr. K. Orzechowski, Charitéplatz 1, 10117 Berlin, Germany; +49 (0)30 450 517222; Ethikkommission@charite.de), ref: EA1/243/20 Norway: Approved 05/11/2020, Regional Committee for Medical and Health Research Ethics (REC), South East (REK Sør-øst D, PO Box 1130, Blindern, N-0318 Oslo, Norway; +47 (0)2284 5511; re-sorost@medisin.uio.no), ref: 166980

Study design

Multicenter hospital-based matched pairs usual-practice wait-list cluster randomized controlled trial with a nested mixed-methods process evaluation

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

The impact of organizational redesign of acute care hospitals according to the Magnet© principles of organizational redesign on mental health and wellbeing of health professionals

Interventions

A multicenter hospital-based matched pairs usual-practice wait-list cluster randomized controlled trial with a nested mixed-methods process evaluation is used. The order in which hospitals receive the intervention is randomized. Using computer-generated randomization with a 1:1 allocation ratio within each country hospitals will be randomized into an immediate intervention group or a usual-practice wait-list control group. Hospitals allocated to the

immediate intervention group, start immediately with the intervention; hospitals in the wait-list group start 12 months later with the intervention. The design of the study inherently makes it impossible to blind hospitals to the intervention.

A multicomponent intervention aimed at organizational redesign of hospitals is applied. Hospitals in the wait-list control group do not access any intervention components until the start of the intervention period in their hospital.

The Magnet4Europe intervention will be launched in the immediate intervention group in month 9 of the project with the first learning collaborative taking place, and will have a total duration of 32 months. The intervention will be initiated in the usual-practice wait-list control group in month 19 and will last for 22 months.

At month 9, hospitals allocated to the immediate intervention group will engage in full exposure to the multi-component intervention. Full exposure entails following active components being operationalised:

- 1. The hospital start the implementation of the Magnet© components as outlined in the Magnet Manual© of organisational redesign. Using the Magnet4Europe Magnet© Gap Analysis Tool they will perform a gap analysis in close collaboration with their assigned twinning partner. Based on the results of the gap analysis, each intervention hospital is responsible for tailoring and individualizing the interventions to their hospital-specific context and develop a concrete, written implementation plan (in collaboration with the twinning hospital) that will be executed during the course of the intervention period
- 2. In close relation to element one of the intervention: hospitals engage in an active one-to-one twinning relationship with a Magnet© designated hospital. Twinning entails bi-annual on-site visits of the Magnet© partner to the intervention hospital (or vice-versa) and monthly virtual meetings
- 3. All hospitals allocated to the immediate intervention group will attend an international Learning collaborative taking place at month 9 (i.e. current plan in protocol)
- 4. The group of intervention hospitals is actively involved in creating critical mass. They promote innovation, draw public interest and foster replication. Tangibility of critical mass is difficult; nonetheless will it serve catalyst for improvement and enables improvements to take hold and to be more sustainable
- 5. Provide near real-time feedback to hospitals on clinicians' reports on work conditions and wellbeing after each of the quantitative data collection periods using rapid document delivery via SAS Output Delivery System. The duration of exposure in the immediate intervention group is 32 months

The intervention in the usual-practice waitlist control group is employed 10 months later compared to the immediate intervention group and is - to a large extent - identical. At month 19 these hospitals engage in full exposure to the different intervention components. The only minor difference can be found in component three: i.e. the usual-practice waitlist hospitals now have access to implementation strategies of hospitals in the immediate intervention group allowing for expeditated implementation of the Magnet© principles. This knowledge is not available for the immediate intervention group. The usual-practice waitlist control group will receive feedback on clinicians' reports on work conditions and wellbeing for the first time. The duration of exposure in usual-practice waitlist control group is 22 months

Intervention Type

Behavioural

Primary outcome(s)

Burnout measured among nurses and physicians using the validated Emotional Exhaustion subscale of the Maslach Burnout Inventory (9-items) and the Burnout Assessment Tool (12-items). Burnout is measured at every measurement occasion, i.e. at month 9, 17, 29 and 41 in the intervention group and the wait-list control group.

Key secondary outcome(s))

Current secondary outcome measures as of 26/05/2020:

Measured among nurses at each measurement occasion i.e. at month 9, 17, 29 and 41 in both the immediate intervention group and the wait-list control group:

- 1. Work engagement (UWES-3)
- 2. Job satisfaction measured using a single question
- 3. Depression (PHQ-2)
- 4. Anxiety (GAD-2)
- 5. General health (SF-8)
- 6. Sleep quality (PSQ)
- 7. Intent to leave the hospital measured using two items
- 8. Absenteeism (HPQ) and presenteeism (HPQ)
- 9. Workability measured using a single question
- 10. Work-life conflict measured using a single question
- 11. Team commitment measured using a single question
- 12. Organizational commitment measured using a single question
- 13. Whether clinicians would recommend the hospital measured using two items
- 14. Work environment (PES-NWI)
- 15. Various measures of staffing and workload (NPQS)
- 16. Safety and quality measured using 10 items
- 17. Necessary nursing care left undone measured using a single question
- 18. Operational failures measured using a single question
- 19. Emotional demands (SIMPH)
- 20. Red tape measured using a single question
- 21. Role conflicts (NPQS)
- 22. Job control measured using a single question
- 23. Skill use measured using a single question
- 24. Value congruence measured using a single question
- 25. Performance feedback measured using three items
- 26. Opportunities for learning and development measured using a single question
- 27. Task variety (QEEW)
- 28. Role clarity (NPQS)
- 29. Intrinsic motivation (WEIMS)
- 30. Additional survey items to quantify associations will be measured among nurses in measurement occasions 2 and 4 (i.e. month 17 and 41) in the wait-list control group:
- 30.1. Emotional dissonance measured using a single question
- 30.2. Qualitative job insecurity measured using a single question
- 30.3. Basic need satisfaction measured using a six items
- 30.4. Engaging leadership measured using a twelve items
- 31. To survey physicians at each measurement occasion in both the immediate intervention group and the wait-list control group (measures as above):
- 31.1. Work engagement
- 31.2. Job satisfaction
- 31.3. Depression

- 31.4. Anxiety
- 31.5. General health
- 31.6. Sleep quality
- 31.7. Intent to leave the hospital
- 31.8. Absenteeism and presenteeism
- 31.9. Work-life conflict
- 31.10. Whether clinicians would recommend the hospital
- 31.11. Work environment
- 31.12. Measures of staffing and workload
- 31.13. Safety and quality
- 31.14. Red tape

Previous secondary outcome measures:

Measured among nurses at each measurement occasion i.e. at month 9, 17, 29 and 41 in both the immediate intervention group and the wait-list control group:

- 1. Work engagement (UWES-3)
- 2. Job satisfaction measured using a single question
- 3. Depression (PHQ-2)
- 4. Anxiety (GAD-2)
- 5. General health (SF-8)
- 6. Sleep quality (PSQ)
- 7. Intent to leave the hospital measured using a single question
- 8. Absenteeism (HPQ) and presenteeism (HPQ)
- 9. Workability measured using a single question
- 10. Work-life conflict measured using a single question
- 11. Team commitment measured using a single question
- 12. Organizational commitment measured using a single question
- 13. Whether clinicians would recommend the hospital measured using a single question
- 14. Work environment (PES-NWI)
- 15. Various measures of staffing and workload (NPQS)
- 16. Safety and quality measured using a single question
- 17. Necessary nursing care left undone measured using a single question
- 18. Operational failures measured using a single question
- 19. Emotional demands (SIMPH)
- 20. Red tape measured using a single question
- 21. Role conflicts (NPQS)
- 22. Job control measured using a single question
- 23. Skill use measured using a single question
- 24. Value congruence measured using a single question
- 25. Performance feedback measured using a single question
- 26. Opportunities for learning and development measured using a single question
- 27. Task variety (QEEW)
- 28. Role clarity (NPQS)
- 29. Intrinsic motivation (WEIMS)
- 30. Additional survey items to quantify associations will be measured among nurses in measurement occasions 2 and 4 (i.e. month 17 and 41) in the wait-list control group:
- 30.1. Emotional dissonance measured using a single question
- 30.2. Qualitative job insecurity measured using a single question

- 30.3. Basic need satisfaction measured using a single question
- 30.4. Engaging leadership measured using a single question
- 31. To survey physicians at each measurement occasion in both the immediate intervention group and the wait-list control group (measures as above):
- 31.1. Work engagement
- 31.2. Job satisfaction
- 31.3. Depression
- 31.4. Anxiety
- 31.5. General health
- 31.6. Sleep quality
- 31.7. Intent to leave the hospital
- 31.8. Absenteeism and presenteeism
- 31.9. Work-life conflict
- 31.10. Whether clinicians would recommend the hospital
- 31.11. Work environment
- 31.12. Measures of staffing and workload
- 31.13. Safety and quality
- 31.14. Red tape

Completion date

30/06/2024

Eligibility

Key inclusion criteria

Hospitals:

- 1. No Magnet© designation by the American Nursing Credentialing Center (ANCC) has been acquired in the past or at the time of the start of the intervention
- 2.Bed size greater or equal to 150
- 3. The hospital is focused on acute care for adults, including at least wards on internal medicine and/or surgery

Health professionals:

- 1. They have direct patient contact
- 2. Meet the minimum qualifications as stipulated by Directive 2013/55/EU amending Directive 2005/35/EC on the recognition of professional qualifications
- 3. Work on adult inpatient units including intensive care units (ICU) and the emergency room (ER)

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

Hospitals:

1. Highly specialized hospitals, e.g. psychiatric hospitals, tropical medicines or pediatrics

Health professionals:

1. Working in neonatology, pediatrics, obstetrics, psychiatry, operating room, pathology, microbiology, radiology and medical imaging

Date of first enrolment

19/10/2020

Date of final enrolment

24/12/2023

Locations

Countries of recruitment

United Kingdom

England

Belgium

Germany

Ireland

Norway

Sweden

Study participating centre University Hospitals Leuven

Belgium 3000

Study participating centre OLV Aalst

Belgium 9300

Study participating centre University Hospitals Brussels Belgium

1090

Study participating centre Ziekenhuis Oost Limburg Belgium 3600

Study participating centre Jessa Ziekenhuis Belgium 3500

Study participating centre RZ Heilig Hart Leuven Belgium 3000

Study participating centre AZ DeltaBelgium
8800

Study participating centre AZ Vesalius Belgium 3700

Study participating centre
OLV van Lourdes Ziekenhuis Waregem
Belgium
8790

Study participating centre AZ Sint-Maarten Belgium 2800 **Study participating centre AZ Maria Middelares**Belgium
9000

Study participating centre AZ Sint-Vincentius DeinzeBelgium
9800

Study participating centre Universitätsklinikum Hamburg-Eppendorf Germany 20251

Study participating centre Universitätsklinikum Heidelberg Germany 69120

Study participating centre Universitätsklinikum Düsseldorf Germany 40225

Study participating centre
Ulm Universitäts und Rehabilitationskliniken
Germany
89081

Study participating centre Universitätsklinikum Münster Germany 48149

Universitatsklinikum Bonn Germany

53127

Study participating centre Johanna Etienne Krankenhaus Kreiskliniken Reutlingen Germany 72764

Study participating centre

Deutsches Herzzentrum München

Germany

80636

Study participating centre
Deutsches Herzzentrum Berlin
Germany
13353

Study participating centre Robert-Bosch-Krankenhaus Germany 70376

Study participating centre Städtisches Klinikum Dessau Germany 06847

Study participating centre Universitätsklinikum Halle Germany 06120

Kalmar Länssjukhus

Sweden 39244

Study participating centre Skåne University Hospital Malmö/Lund Sweden 20501

Study participating centre Uppsala University Hospital Sweden 75185

Study participating centre Lovisenberg Diakonale Sykehus Norway 0456

Study participating centre Beaumont Hospital Ireland D09 V2N0

Study participating centre Connolly Hospital Ireland D15 X40D

Study participating centre Cork University Hospital Ireland T12 DFK4

Galway University Hospital Ireland H91 YR71

Study participating centre Letterkenny University Hospital Ireland X75 8X8

Study participating centre Limerick University Hospital Ireland V94 F858

Study participating centre
Our Lady of Lourdes Hospital
Ireland
A92 VW28

Study participating centre South Infirmary-Victoria University Hospital Ireland T12 X23H

Study participating centre St. James's Hospital Ireland D08 NHY1

Study participating centre Tipperary South Hospital Ireland E91 VY40

Waterford University Hospital Ireland

X91 ER8E

Study participating centre Tallaght University Hospital Ireland D24 NR0A

Study participating centre Mater Misericordiae University Hospital Ireland D07 R2WY

Study participating centre Bons Secours Hospital Ireland D09 YN97

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East and North Hertfordshire NHS Trust
United Kingdom
SG1 4AB

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Study participating centre
Torbay and South Devon Health Care NHS Foundation Trust
United Kingdom
TQ2 7AA

West Hertfordshire Hospitals NHS Trust

United Kingdom WD18 0HB

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Bradford Teaching Hospitals NHS Foundation Trust
United Kingdom
BD9 6RJ

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LA9 7RG

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Klinikum Osnabrück

Germany 49076

Study participating centre Universitaetsklinikum Regensburg Germany 93053

Study participating centre Kreiskliniken Reutlingen Germany 72764

Study participating centre Krankenhaus vom Roten Kreuz Bad Cannsatt Germany 70372

Study participating centre Sana Herzchirurgie Stuttgart Germany 70174

Study participating centre Universitätsklinikum Tübingen Germany 72076

Study participating centre Städtisches Klinikum Lüneburg Germany 21339

Klinikum Bremerhaven-Reinkenheide

Germany 27574

Study participating centre Mercy University Hospital Ireland T12 WE28

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United Kingdom
GU16 7UJ

Study participating centre

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
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DN2 5LT

Study participating centre Chelsea and Westminster Hospital NHS Foundation Trust United Kingdom SW10 9NH

Study participating centre King's College Hospitals NHS Foundation Trust United Kingdom SE5 9RS

Study participating centre
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United Kingdom
TS4 3BW

Lancashire Teaching Hospitals

United Kingdom PR2 9HT

Study participating centre Södertälje Sykehus Södertälje Sweden 152 40

Sponsor information

Organisation

KU Leuven

ROR

https://ror.org/05f950310

Funder(s)

Funder type

Government

Funder Name

European Commission Horizon 2020

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 15/10/2025 | 04/11/2025 | Yes | No |
| <u>Protocol article</u> | | 28/07/2022 | 29/07/2022 | Yes | No |
| Interim results article | | 15/01/2024 | 16/01/2024 | Yes | No |

Participant information sheetParticipant information sheet11/11/202511/11/2025NoYesStudy website11/11/202511/11/2025NoYes