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

Submission date 31/03/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/04/2020	**Overall study status** Completed	
Last Edited 16/01/2024	**Condition category** 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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Study website
http://www.magnet4europe.eu/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
274132

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request participant information sheet.

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 measure
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.

Secondary outcome measures
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

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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

Overall study start date
01/01/2020

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

Age group
Adult

Sex
Both

Target number of participants
Power and sample size calculation was performed for the primary outcome of interest, i.e. burnout, exemplified by using the emotional exhaustion subscale of the Maslach Burnout Inventory. In total 10,253 participants divided in 51 clusters with an average cluster size of 200 are required per measurement occasion.

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
Belgium

England

Germany

Ireland

Norway

Sweden

United Kingdom

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 Delta
Belgium
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 Deinze
Belgium
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

Study participating centre
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

Study participating centre
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

Study participating centre
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

Study participating centre
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

Study participating centre

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SG1 4AB

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Gloucestershire Hospitals NHS Foundation Trust
United Kingdom
GL53 7AN

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

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West Hertfordshire Hospitals NHS Trust
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Kreiskliniken Reutlingen
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Study participating centre
Krankenhaus vom Roten Kreuz Bad Cannsatt
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70372

Study participating centre

Sana Herzchirurgie Stuttgart
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Universitätsklinikum Tübingen
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Study participating centre
Städtisches Klinikum Lüneburg
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Study participating centre
Klinikum Bremerhaven-Reinkenheide
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27574

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Frimley Health NHS Foundation Trust
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Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
United Kingdom
DN2 5LT

Study participating centre

Chelsea and Westminster Hospital NHS Foundation Trust
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SW10 9NH

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

Study participating centre
South Tees Hospitals NHS Foundation Trust
United Kingdom
TS4 3BW

Study participating centre
Lancashire Teaching Hospitals
United Kingdom
PR2 9HT

Study participating centre
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Södertälje
Sweden
152 40

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Sponsor type

University/education

Website
https://www.kuleuven.be/samenwerking/ligb/Home

ROR
https://ror.org/05f950310

Funder(s)

Funder type
Government

Funder Name
European Commission Horizon 2020

Results and Publications

Publication and dissemination plan
Magnet4Europe has a strong focus on strengthening the evidence on the impact of work environment on mental health of health professionals. Findings will be published in peer reviewed journals and through other channels designed to reach a diverse community of researchers, practitioners, and other stakeholders. Gold open access will be used for the key findings of the study to ensure maximum exposure to a practice community. Beyond the funded life of the project the aim is to maximize accessibility by fully exploiting the opportunity for green open access and, where possible, identifying additional funds to support further gold open access. The study protocol is the first publication aimed for in this project.

Intention to publish date
30/09/2024

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?
Protocol article		28/07/2022	29/07/2022	Yes	No
Interim results article		15/01/2024	16/01/2024	Yes	No