

BMJ Open A workplace organisational intervention to improve hospital nurses' and physicians' mental health: study protocol for the Magnet4Europe wait list cluster randomised controlled trial

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ABSTRACT

Introduction The increasing burden of mental distress reported by healthcare professionals is a matter of serious concern and there is a growing recognition of the role of the workplace in creating this problem. Magnet hospitals, a model shown to attract and retain staff in US research, creates positive work environments that aim to support the well-being of healthcare professionals.

Methods and analysis Magnet4Europe is a cluster randomised controlled trial, with wait list controls, designed to evaluate the effects of organisational redesign, based on the Magnet model, on nurses' and physicians' well-being in general acute care hospitals, using a multicomponent implementation strategy. The study will be conducted in more than 60 general acute care hospitals in Belgium, England, Germany, Ireland, Norway and Sweden. The primary outcome is burnout among nurses and physicians, assessed in longitudinal surveys of nurses and physicians at participating hospitals. Additional data will be collected from them on perceived work environments, patient safety and patient quality of care and will be triangulated with data from medical records, including case mix-adjusted in-hospital mortality. The process of implementation will be evaluated using qualitative data from focus group and key informant interviews.

Ethics and dissemination This study was approved by the Ethics Committee Research UZ/KU Leuven, Belgium; additionally, ethics approval is obtained in all other participating countries either through a central or decentral authority. Findings will be disseminated at conferences, through peer-reviewed manuscripts and via social media.

Trial registration number ISRCTN10196901.

INTRODUCTION

Mental health and well-being are high priorities for the European Union (EU).¹ Mental health conditions account for 22% of the

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Magnet4Europe uses a cluster randomised controlled trial design with wait list controls in over 60 hospitals in six European countries.
- ⇒ A multicomponent strategy is used to support implementation of a complex intervention at the hospital level, aimed to improve clinician well-being.
- ⇒ The Magnet4Europe intervention is tailored to European hospitals, facilitating implementation and transferability without disrupting clinical practice.
- ⇒ Contextual factors such as different health systems within and across countries may impact the standardised Magnet4Europe intervention and unintentionally lead to variation in the intervention and outcomes.
- ⇒ Embedding a complex intervention at hospital-level takes time and any effect might become apparent only after the study ends.

EU's disease burden measured in Years Lived with Disability, thus imposing a significant burden on individuals, society and the economy.² Health workers experience greater levels of job-related burnout and other mental health disorders than those in other sectors.^{3 4} An earlier European study of working conditions in European hospitals, identified high rates of job dissatisfaction and burnout, with burnout rates among nurses varying from 10% to 78%^{5 6} while the corresponding figures from studies of physicians ranged from 25% to 60%, varying among organisations and medical specialties.⁷⁻¹⁰ Burnout in the healthcare workforce not only



impacts on those experiencing it, leading to depression, substance abuse and even suicide^{11–15} but is also associated with worse patient outcomes, lower patient satisfaction,⁶ medical errors,¹⁶ reduced quality and safety¹⁷ and reduced efficiency of hospitals.¹⁸ The resulting lost productivity, combined with current recruitment challenges, further threatens the already overstretched health workforce, widening the gap between provision of health services and population needs.¹⁹

This situation has been exacerbated by the COVID-19 pandemic,²⁰ increasing anxiety and stress among clinicians²¹ and further impacting on health workers' mental health.^{22–24}

Effective, affordable and sustainable interventions to improve health professionals' mental health and well-being are essential if we are to interrupt the vicious cycle of high burnout, worsening mental health, lost productivity and unsafe care.²⁵ Interventions to prevent burnout can be divided into two types: first, psychological interventions aimed at individual level and second workplace redesign. There is only limited evidence of the impact of individual psychological approaches to improve resilience and coping skills (eg, mindfulness).²⁶ The second approach, redesigning the organisational environment in which health professionals provide care, aims to reduce modifiable sources of clinician stress and burnout, reinforce clinicians' perceptions of well-being and enhance their autonomy and control over the conditions of their work. There is substantial research pointing to organisational redesign as the most promising of these two approaches.²⁷

The finding that the causes underlying burnout in nurses and physicians are similar and, especially, are rooted within the work environment^{28–31} provides a compelling rationale for prioritising the redesign of hospital environments to address this issue. In the 1980s, hospitals in the USA were faced with high nurse turnover,^{32 33} low retention, and increasing early retirement rates.³⁴ Despite the general nursing shortage, some US hospitals—later referred to as Magnet hospitals—were more successful in recruiting and retaining nurses by creating a positive work environment. Features characterising these hospitals included flat decentralised organisational structures, empowering frontline staff in decision-making and transformational leadership.³⁵ The original characteristics of these hospitals³⁶ were developed into 14 forces of Magnetism and later configured into 5 components of the Magnet model that was used to establish the criteria for Magnet designation.³⁷ A robust body of evidence, primarily stemming from US hospitals, documents the association of the Magnet model with improved well-being of staff, including lower burnout, higher job satisfaction, lower intent to leave their job,^{38 39} in addition to positive financial outcomes for organisations,^{40 41} higher levels of patient satisfaction^{42 43} and improved clinical outcomes.^{44 45} Longitudinal panel studies have found that hospitals that follow the Magnet model improve their work environments, well-being of staff and patient

outcomes, compared to other hospitals. Two international pilots tested the transferability of the Magnet model, demonstrating the feasibility of achieving positive results outside the USA. One, in England, focused primarily on the implementation of the Magnet process.⁴⁶ The other, a four-hospital intervention with accompanying evaluation in Russia and Armenia, used the Magnet model with twinning with Magnet recognised hospitals.⁴⁷ In both cases, the intervention hospitals improved their work environments substantially from their baselines within the 2-year intervention and achieved better outcomes for staff, such as reduced dissatisfaction, intent to leave and emotional exhaustion (EE), while perceived quality of care improved. Despite the large body of evidence and recent uptake in two European hospitals, Magnet organisational redesign initiatives have not been adopted widely in Europe.

The aim of the Magnet4Europe project is to evaluate the ability of organisational redesign in European hospitals to improve nurses' and physicians' mental health and well-being. The organisational redesign intended in Magnet4Europe is a system-level intervention, targeting the hospital as a whole on the level of the organisation. Through co-creation and stakeholder co-designed adaptations, the Magnet model is adapted to the European context, providing the first element and basis for the Magnet4Europe intervention. In addition to this first component, one-to-one twinning with Magnet recognised hospitals, learning collaboratives and a critical mass of hospitals are also introduced into the intervention. While the Magnet4Europe intervention shares common elements with other organisational interventions, the combination of all the above components, targeting two major clinical professions—both nurses and physicians—and its primary focus on the work environment as levers for change differentiate the Magnet4Europe intervention from any other organisational intervention and make it unique in its kind.⁴⁸

METHODS AND ANALYSIS

Study design and setting

Magnet4Europe will use a usual-practice cluster randomised controlled trial with wait list controls in a nested mixed-methods evaluation. The study protocol for this study follows 'the Standard protocol items: recommendations for intervention trials 2013 statement' (SPIRIT, online supplemental file 1).⁴⁹ The setting will be acute general hospitals in six European countries, including both EU member states (Belgium, Germany, Ireland and Sweden) and non-EU member states (England and Norway). These six countries also represent two dominant types of health systems, ie, Bismarck and Beveridge,⁵⁰ that vary with regards to the extent of national government intervention in health services delivery, something that may be a factor in uptake of innovation.

Eligibility

European hospitals are eligible to participate if: (1) no Magnet designation by the American Nursing Credentialing Centre (ANCC) had been acquired in the past or at the time of the start of the intervention, (2) bed size ≥ 150 and (3) the hospital is focused on acute care for adults, including wards in the area of internal medicine and/or surgery. Excluded are highly specialised hospitals, for example, psychiatric hospitals, tropical medicine or paediatrics.

Within each hospital, registered nurses and physicians (including residents) will be eligible to participate in the quantitative and qualitative evaluation of the intervention if they: (1) have direct patient contact, (2) meet the minimum qualifications as stipulated by Directive 2013/55/EU amending Directive 2005/36/EC on the recognition of professional qualifications and (3) work on adult inpatient units including intensive care units and the emergency room. Nurses and physicians working in specialised units such as neonatology, paediatrics, obstetrics, psychiatry, operating room, pathology, microbiology, radiology and medical imaging will be excluded.

Study sample

A two-phased non-probability strategy will be used to sample organisations at the hospital level. First, in February and March 2019, principal investigators in the six European countries contacted eligible hospitals (see below) within those countries to consider taking part in the study using various recruitment strategies. Hospitals were informed of the Magnet4Europe objectives and methodology and were invited to show their interest in participating by submitting a letter of intent by March 2019. In spring 2020, participating hospitals (some of the original expression of interest sites and other new ones) were asked to confirm their commitment by signing an agreement committing to participate for the full duration of the study period and adhere to the Magnet4Europe protocol.

Sample size will be determined based on the power calculation for a cluster randomised controlled trial with before-and-after measures.⁵¹ The calculated design effect is based on average cluster size and the intraclass correlation coefficient (ICC), a measure of the amount of dependency among observations within classes (ie, hospitals in our study).^{51 52} Power calculation will be performed for the primary outcome of interest, burnout, measured by the EE subscale of the Maslach Burnout Inventory (MBI).⁵³ The estimated prevalence rate of EE is 30% based on the team's earlier RN4CAST study.⁶ In order to detect a 20% relative reduction (ie, a 6 percentage point reduction) in burnout with a power of 80% and an alpha of 5%, an average cluster size of 200 and an ICC of 0.025,⁵⁴ this study will require 10 253 health professionals in 51 clusters per measurement occasion (at endpoint of the study).

Based on the power calculation, we aim to include 60 general acute care hospitals in six countries (Belgium,

England, Germany, Ireland, Norway and Sweden) and recruit at least 200 professionals per hospital.

Randomisation

Randomisation to intervention and control group is at the hospital level. Within each country, hospitals will be matched on three characteristics, (1) bed size, (2) teaching status and (3) high technology, using a Euclidian distance matrix based on the smallest within pair covariate distance. Subsequently, simple random sampling—allowing for selection with equal probability—will be used to allocate one hospital within each matched pair of hospitals to the immediate intervention group or the wait list control group. Both immediate intervention group and wait list controls will be informed which group they have been allocated to. Given the characteristics of the intervention in which active participation of the hospitals is required, blinding to the intervention will not be possible.

Intervention

A multicomponent intervention comprising organisational redesign of hospitals will be implemented in both arms of the study. The intervention was launched in the immediate intervention group in month 10 of the project (October 2020) and will have a total duration of 31 months. The intervention in the usual-practice wait list control group will be initiated in month 17 (May 2021) and will last for 24 months (figure 1).

The intervention consists of five distinct components: The Magnet blueprint, one-to-one twinning between European hospitals and US Magnet designated hospitals, learning collaboratives involving group meetings to share best practices, critical mass and communication and feedback.

The first part of the intervention comprises the elements outlined in the Magnet manual of organisational redesign. This contains a step-by-step blueprint through the five overarching Magnet components: (1) structural empowerment of clinical staff, (2) transformational leadership, (3) exemplary and evidence-based professional practice, (4) new knowledge, innovations and improvements and (5) empirical outcomes. These principles serve as continuous feedback loops as to whether organisational changes are producing the intended outcomes for health professionals and patients. The manual provides definitions of the principles and gives examples of evidence-based indicators that reflect progress towards achieving them. Using the Magnet4Europe Gap Analysis Tool (adapted from the ANCC Magnet Gap Analysis tool), each participating European hospital will, in collaboration with their Magnet twinning partner, perform a gap analysis that will illuminate the gap between the as-is situation and the aspirational organisational features as delineated in the Magnet blueprint. The tool should be used for initial and continuous assessment of workplace redesign. This will increase the ability of hospitals to identify and prioritise learning and infrastructure needs, while also identifying

healthcare.^{61 62} Critical mass also maximises the network exchanges and opportunities for feedback that arise out of other elements of our intervention such as the learning collaborative. This is supported by recent experience with the Magnet model.^{63 64}

A fifth component of the intervention is to provide regular survey feedback to hospitals on clinicians' reports on work conditions and well-being on the hospital level, separately for physicians and nurses.⁶⁵ Hospitals will be anonymised using a randomly generated letter code allowing each hospital to identify themselves but not any of the other hospitals. Data will only be reported in aggregated form and will not highlight a single individual's data.

Evaluation of the effect of the intervention

A mixed-methods evaluation will be conducted to examine the effect of the intervention, including quantitative and qualitative components.

The guiding framework for our quantitative evaluation is the Quality Health Outcomes Model—as adapted by Aiken and colleagues⁶⁶—based on a conceptual framework that sets out mechanisms relating organisational attributes to clinician and patient outcomes. Their model is theoretically founded on Donabedian's early conception of associations between structures, processes and outcomes⁶⁷ including the dynamism between model components that was proposed in the Health Quality Outcomes Model.⁶⁸ The Job Demands-Resources model also informed the choice of survey items, seeking to understand the intervention's impact on the imbalance between demands on the clinician and the resources available to clinicians to deal with these demands.⁶⁹ Job demands refer to aspects of the job that require sustained physical or mental effort and are associated with certain physiological and psychological costs. Job resources describe aspects of the job that are related to achieving work goals, reducing job demands and the associated physiological and psychological costs and stimulating personal growth and development.

The qualitative part of the study aims first, to evaluate the implementation process, adaptation, reach and quality as well as mechanisms of impact manifested in participants' responses, mediators, unexpected pathways and consequences; and second, to explore barriers and enablers of the implementation and the experiences of the change process from the perspectives of health professionals and persons involved in leading the implementation.⁷⁰

Quantitative evaluation

Quantitative data collection

Quantitative data collection across countries is standardised using an online data collection platform. Quantitative survey data will be collected at three points in time, that is, at baseline (T0) in months 11–12 of the project timeline, at T1 (months 28–29) and T2 (months 41–42) (figure 1) during an 8week period. An open cohort design will be employed in which all eligible nurses and

physicians are invited to participate in each of these three measurement points (T0–T2). Nurses and physicians will be recruited within each hospital at baseline and will be asked to participate in surveys with repeated measures taken over the three points in time allowing partially longitudinal follow-up of a cohort of individuals. Initial non-participants and new employees will be invited to join the study at later measurement points. Regular reminders will be sent to any clinicians (registered on the platform) through the online data collection platform who have not or only partially completed the survey. Individual informed consent for participation will be obtained by the researchers at the first contact (online supplemental file 2). Each record of informed consent is retained on the online platform.

Quantitative measures

The main survey for nurses and physicians contains a core set of outcomes and main explanatory and process variables directly linked to the Magnet4Europe Magnet Gap Analysis Tool. All study measures are based on validated instruments.

All survey items will be translated in Dutch, English, German, Norwegian and Swedish. When available, validated translations of instruments will be used. If no validated translation is available, a prespecified translation procedure will be applied. First, a forward translation will be performed by a researcher involved in this research; the language in which the item is translated is the native language of the researcher. Second, other researchers within the country research group will thoroughly assess the forward translation in multiple phases until consensus is reached on each item.

Primary outcome

Burnout is the primary outcome measure and will be measured on individual level using the 9-item EE subscale of the MBI.⁵³ In addition, the Burnout Assessment Tool (BAT), a 12-item novel self-report questionnaire will also be used to measure burnout.^{71–73} The combination of both instruments to assess burnout, allows for: (1) a direct comparison of levels of EE with previous studies in the medical field (using the EE-subscale of MBI) and (2) an up-to-date assessment of the more comprehensive burnout syndrome as well as a reliable estimation of the number of respondents with severe burnout symptoms and a comparison with the level of burnout of the national workforce.

Covariates

Secondary outcome measures include work engagement (UWES-3),⁷⁴ job satisfaction,^{75 76} depression (PHQ-2),⁷⁷ anxiety (GAD-2),⁷⁸ general health (SF-8),⁷⁹ sleep quality (PSQ),⁸⁰ intent to leave the hospital,^{75 76} absenteeism and presenteeism (HPQ),¹⁴ workability, work-life conflict, team commitment, organisational commitment,⁸¹ and whether clinicians would recommend the hospital.



Core exploratory variables include work environment (PES-NWI),⁸² various measures of staffing and workload (NPQS),⁸³ care left undone,⁸⁴ operational failures, emotional demands (SIMPH),⁸⁵ red tape,⁸⁶ role conflicts (NPQS), job control, skill use, value congruence, performance feedback, opportunities for learning and development⁸⁷ and intrinsic motivation (WEIMS).⁸⁸

Supplementary survey items are used to test more specific hypotheses.^{69 89} These items contain measures on qualitative job insecurity,⁹⁰ emotional dissonance,⁹¹ task variety (QEEW),⁹² role clarity (NQPS),⁸³ basic need satisfaction⁹³ and engaging leadership.⁹⁴

Productivity measures consist of staff turnover rate, sickness absence rate, number of vacancies and the use of agency staff—measured at organisation level—complemented by previously mentioned secondary outcome measures, for example, absenteeism and presenteeism are measured at individual level by means of a survey. Productivity measures evaluated at the level of the organisation are evaluated over the period of 1 calendar year. The timeframe to evaluate absenteeism on individual level is 28 days, ie, participants are asked to indicate the number of scheduled work days they have missed during the past 28 days. The timeframe to evaluate presenteeism on individual level is 1 year.

Data analysis

Regression models to estimate the association between the intervention and outcomes will include fixed effects of time, intervention and intervention by time. Hospitals represent higher order units of analysis, and clinicians the lower order unit of analysis. Countries will be treated as fixed effects. Repeated measures on nurses and physicians will also be appropriately modelled. More complex multilevel structural models will be employed to examine indirect and moderated associations between the process measures which we would expect to respond to the intervention and our outcome measures. All analyses will be conducted according to intention-to-treat. Data on hospital characteristics (eg, size, teaching status) and clinicians (eg, gender, age) will be collected and used to adjust for potential confounders in the regression analyses. Statistical significance will be assessed at the 5% level. Occasional missing data will be limited by the electronic survey implementation using a force response option for each item. Data analysis will be conducted using SAS software, V.9.4 (and subsequent releases) of the SAS system for windows (SAS Institute, Cary, North Carolina).

Process evaluation

Qualitative data collection

Data will be collected on context, implementation and mechanisms of impact. Based on the results at baseline measurement, a purposive sample of two hospitals per country will be selected from the immediate intervention group for case studies to explore different aspects of the implementation process. Hospitals with the lowest burnout scores among clinicians will be contrasted with

hospitals with the highest to explore potential differences in motivation and ambition in the hospitals. In total, four qualitative data collection periods are planned throughout the project (figure 1). Two focus group interviews (one with 6–8 nurses and one with 6–8 physicians) will be conducted in each of the two case hospitals (per country) at one point in time (M34-35). This will generate 20 focus groups in total across all countries. A purposive sampling approach is used to recruit participants. We will invite physicians and nurses who work in direct patient care in clinical areas targeted by the Magnet intervention and most closely involved in implementing change. By doing so, we will aim for diversity within each staff group in terms of clinical areas and length of clinical experience. If focus groups cannot be convened (eg, recruitment difficulties), then each focus group will be replaced with 2 to 3 one-to-one interviews with similar staff types to the target focus group sample. Depending on practicalities, this may result in a data set that is generated from focus groups and/or one-to-one interviews. A minimum of 40 and maximum of 160 individuals will be involved in this part of the study.

In addition to the focus groups, two semi-structured individual interviews will be conducted at three time points (months 23, 34 and 44) in each of the two case hospitals (per country). Persons directly involved in leading the implementation, that is, the Magnet4Europe intervention coordinator as well as another member of the interdisciplinary Magnet council will be invited to participate. This will lead to 60 interviews in total (across countries) over the course of the project. Where possible, we aim to interview the same two people across all time points. If individuals leave the study, we will aim to recruit a replacement with a similar role and professional background. We will also aim for maximum diversity in professional backgrounds, for example, one from nursing, one from medicine. A minimum of 30 and a maximum of 60 individuals will be involved in this part of the study.

To complement the qualitative evaluation, the 12-item Organisational Readiness for Implementing Change (ORIC) scale⁹⁵ and the 23-item Normalisation Measure Development Questionnaire (NoMAD)^{96 97} will be used to explore the readiness for change and the extent to which Magnet is integrated and sustained in the hospital over time. This will be done after the start of the intervention and at various time points. Magnet4Europe intervention coordinators and all other members of the interdisciplinary Magnet4Europe council in all hospitals will be invited to respond to the surveys. A minimum of 54 and a maximum of 324 individuals across all countries will be involved in this part of the study at each time point. If individuals leave and are replaced, their replacements will be invited to complete the survey on the next occasion.

Qualitative data analysis

Analysis of the qualitative data generated through focus groups and individual interviews will be guided by the

Box 1 Magnet4Europe implementation evaluation

Context

- ⇒ General information about the hospital (eg, type of hospital, size, organisational models, professional structure).
- ⇒ Hospital policy documents (eg, about staffing, work environment, leadership development, organisational plans).
- ⇒ General country information (eg, relevant legislation, financing of the healthcare sector).

Implementation

- ⇒ Results from the Magnet4Europe Magnet Gap Analysis Tool and the work plan of each hospital.
- ⇒ Implementation process survey data.
- ⇒ Data from interviews and focus groups.

Mechanisms of impact

- ⇒ Hospital policy documents (eg, staffing, work environment, leadership development, organisational plans).
- ⇒ Implementation process survey data.
- ⇒ Data from interviews and focus groups.

Framework Analysis approach.⁹⁸ Data collection and analysis will be conducted by researchers in each of the Magnet4Europe countries, using a common coding template, which will be developed based on initial themes. International meetings will be held regularly to discuss analysis and findings. NVivo V.12 (and subsequent releases) will be used for management and analysis of qualitative data.⁹⁹

Data generated through collection of policy documents and general hospital information about context will be analysed through content analysis and/or discourse analysis¹⁰⁰ to explore different aspects of the organisational context in relation to the implementation process.

In the process evaluation, we will analyse how organisational context links to the impact and sustainability of the Magnet programme. Emerging themes from the qualitative analysis will be used, together with the results from descriptive analyses of our quantitative measurements of readiness for change and of implementation normalisation (NoMAD instrument), to explain variations in implementation between and within individual settings over time (box 1).

Patient and public involvement

Patients and/or public were not involved in the design or development of research questions of this study.

ETHICS AND DISSEMINATION

Ethics

This study was approved by the Ethics Committee Research UZ/KU Leuven, Belgium; additionally, ethics approval is obtained in all other participating countries either through a central or decentral authority, to conduct nurse surveys as well as collect qualitative data. Any protocol amendments will be promptly reported to all relevant parties. An Ethical Advisory Committee was installed at the start of project and includes an

independent ethics advisor with documented expertise to monitor ethics issues. The study is registered in the ISRCTN registry.

Dissemination

Magnet4Europe has a strong focus on disseminating 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 maximise accessibility by fully exploiting the opportunity for green open access and, where possible, identifying additional funds to support further gold open access publishing. Data management is compliant in line with the European Commission's Horizon 2020 Data Management Plan guidelines and FAIR-principles.

DISCUSSION

This paper describes the theoretical framework, conceptual design and methodological approaches of the EU H2020 Magnet4Europe project, which aims to evaluate the transfer, implementation, scale up and cost-effectiveness of the Magnet model of organisational redesign in a European context as a system-level approach to improve clinician well-being. Mental health and well-being is among one of the highest priorities of the public health agenda in the EU.¹ This is based on the growing awareness and recognition of the magnitude of mental health problems and the burden on individuals, society and economy. With the extraordinary conditions created by the COVID-19 pandemic, this issue has taken an even more central role in the policy landscape.²⁰ COVID-19 is expected to have psychological impacts for health professional, in particular, frontline workers that will be sustained over time.^{101–104}

The research activities conducted within the project are expected to improve significantly the work environment of health professionals in hospitals, especially after the COVID-19 pandemic. In particular, Magnet4Europe proposes an organisational intervention, targeting the root of many of the problems (ie, organisational and work-related stressors) facing health systems rather than focusing narrowly of their symptoms. It does so by means of a multicentre study involving more than 60 hospitals across six European countries. By choosing a cluster randomised controlled design, this study is the first with the power to identify a causal association between implementing healthy workplace characteristics and improved staff well-being in European hospitals on a large scale. Two international pilot initiatives testing the transferability of Magnet key principles and accompanied by rigorous evaluations have informed the design of Magnet4Europe.^{46 47} In both, the intervention hospitals improved their work



environments substantially from their baselines at the end of the 2-year intervention, and outcomes for staff improved. The Magnet4Europe intervention builds on lessons learnt from these pilot initiatives. The degree of innovation can also be seen in the use of a multifaceted implementation strategy involving one-to-one twinning with international Magnetdesignated hospitals, creation of a critical mass, co-creation of solutions, development of learning collaboratives, benchmarking and interdisciplinary and management buy-in. In addition, Magnet4Europe makes a strong scientific contribution as it goes beyond traditional studies, which focus solely on individual professions and disciplines separately. This allows us to study the interaction between physicians and nurses working in teams and the impact of healthy environments on their well-being and patient outcomes.

Magnet4Europe will also allow countries to learn from the experience of other health systems and understand the factors influencing their sustainability, as the study will be undertaken in six European countries representing the two dominant health system forms. The so-called Beveridge countries (England, Ireland, Sweden, Norway) are tax funded resulting in potentially more government health policy decision-making while the so-called Bismarck countries (Belgium, Germany) have an employer-based social insurance financing system, which potentially allows for more organisational variation. This study allows us to compare and contrast the impact of healthcare systems on the implementation and sustainability of the intervention.

The project involves dissemination and stakeholder engagement. Various stakeholders will be involved in the project including designees from international and European organisations who represent nursing professionals, healthcare employers, patients and governments. Their main role is to raise awareness of the project and to support dissemination of the results as well as the Magnet4Europe consortium in formulating policy recommendations based on the scientific results.

Limitations

Contextual factors inherent to the countries where Magnet4Europe will be implemented, more specifically different health systems within and across countries, may impact the potential for uptake of the intervention and unintentionally lead to variation in the intervention and outcomes. Certain healthcare system characteristics such as labour supply policies, education requirements and funding schemes may interact with the intervention. In predominantly Beveridge-type system countries, the interaction between these characteristics and the intervention may lead to a more cumbersome process of change and innovation compared with countries with a more decentralised insurance-based health system.

Despite having a strong conceptual design for the Magnet4Europe study, that is, a cluster randomised controlled trial, bearing many advantages and having the potential to facilitate the robust evaluation of this type

of intervention, this design is susceptible to multiple sources for potential risk of bias. First, contamination of the wait list control group cannot be ruled out. All hospitals were, prior to the start of the intervention, informed about the intervention and the active components. It was not possible to blind hospitals to their allocation in either the immediate intervention group or wait list control group. We aimed to mitigate contamination of hospitals assigned to the wait list control group by not providing them with the Magnet blueprint of organisational redesign and by not disclosing the name of their future Magnet twinning partner to avoid early contact and exchange of information prior to their actual start of the intervention. A second additional risk related to contamination is when the intervention takes longer to be fully embedded as intended. The intervention proposed in Magnet4Europe is a complex intervention at the hospital level, earlier research findings demonstrated that a considerable amount of time is required for the intervention to become fully embedded into practice and influence outcomes accordingly. Due to the limited time frame available in Magnet4Europe, no transition period is incorporated. This potential risk is mitigated by two intervention components, that is, the one-to-one twinning of the European intervention hospitals with a designated and experienced US Magnet hospital and the Learning Collaboratives. Both components are expected to act as a catalysator for knowledge transfer and innovation and expedite the implementation of the intervention. There is a potential risk that the true effect of the intervention only becomes apparent after the formal ending of the 4-year study period. A longer follow-up of the study beyond the funding is foreseen.

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Supplementary File 1 - SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	<u>1</u>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	<u>2, 17</u>
	2b	All items from the World Health Organization Trial Registration Data Set	<u>2, 6, 7</u>
Protocol version	3	Date and version identifier	<u>N/A</u>
Funding	4	Sources and types of financial, material, and other support	<u>20</u>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	<u>1, 20</u>
	5b	Name and contact information for the trial sponsor	<u>20</u>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	<u>20</u>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	<u>N/A</u>

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	<u>4-5</u>
	6b	Explanation for choice of comparators	<u>4-5</u>
Objectives	7	Specific objectives or hypotheses	<u>6</u>
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	<u>6</u>

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	<u>6</u>
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	<u>6</u>
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<u>9-12</u>
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	<u>12</u>
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	<u>N/A</u>
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	<u>N/A</u>
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	<u>12-16</u>
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	<u>8</u>

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	<u>7</u>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>7, 12</u>

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	<u>7-8</u>
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	<u>7-8</u>
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>7-8</u>
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>N/A</u>
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	<u>N/A</u>

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	<u>8, 11-16</u>
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	<u>12</u>

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	<u>17</u>
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	<u>14-16</u>
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	<u>14-16</u>
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	<u>14</u>
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	<u>N/A</u>
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	<u>N/A</u>
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	<u>N/A</u>
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>N/A</u>
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>2, 17</u>
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	<u>17</u>

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	<u>12</u>
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	<u>N/A</u>
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	<u>suppl. material #2</u>
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	<u>20</u>
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	<u>17</u>
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	<u>N/A</u>
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	<u>17</u>
	31b	Authorship eligibility guidelines and any intended use of professional writers	<u>17</u>
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	<u>17</u>
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	<u>12, suppl. material #2</u>
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	<u>N/A</u>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

Supplementary File 2 – Participant information sheet and consent form for quantitative (p. 2-3) and qualitative data collection (p.4-5) (English version – Example)

Magnet4Europe - Improving Mental Health and Wellbeing in the Health Care Workplace

Dear colleague,

you have been invited to take part in a research study that aims to improve mental health and wellbeing among health professionals in Europe. The project is funded under the European Union's Horizon 2020 Research and Innovation programme from 2020 to 2023 (Grant Agreement 848031). The study will be conducted in compliance with your country's ethics guidelines for scientific studies on individuals. Your participation will neither involve costs nor reimbursements. You can withdraw from the study at any time, without giving a reason. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and to decide whether you wish to take part or not. Ask us if there is anything that is not clear or if you would like to receive more information. For questions, please reach out to the Magnet4Europe project coordinator prof. dr. Walter Sermeus at walter.sermeus@kuleuven.be.

What is the purpose of the study?

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.

How does this research study work?

This research study will be carried out between January 2020 and December 2023 in adult inpatient units. The intervention itself will officially start in September 2020 in participating European hospitals and will target the five overarching principles of the Magnet® concept: structural empowerment of clinical staff, transformational leadership, exemplary and evidence-based professional practice, new knowledge, innovations, and improvements, and empirical outcomes. These principles will serve as a continuous feedback loop as to whether organizational changes are producing the intended outcomes for staff and patients. The Magnet® blueprint provides definitions of the principles and gives examples of evidence-based indicators that reflect progress toward achieving them. To facilitate the implementation process, each participating European hospital receives support by one to one twinning with an experienced Magnet recognized hospital including annual on-site visits and by the creation of a critical mass of participating hospitals drawing public interest and promoting innovation, and replication. Before the intervention period officially starts, eligible participants will receive a link to the online platform Meplis Care Monitor via mail in May/June 2020. Following the link, they will be able to register first and then to complete a questionnaire. Within the scope of this questionnaire participants will be asked about various aspects of their work environment (work relations, job satisfaction, perception of the quality of care and workload) and mental health. In the course of the study, this procedure will be repeated annually for a total of 4 measurement occasions. In addition to the surveys, occasional focus groups (i.e., moderated interactive group discussions) will take place in a selection of hospitals between July 2021 and September 2023. The focus groups aim to understand clinicians' personal views and thoughts on the process of the intervention and to identify barriers and facilitators to implementation of the intervention.

Why have I been invited and am I eligible?

60 hospitals across the five European countries being involved have agreed to participate in this study. Within each participating hospital, all adult inpatient units including ICU and ER have been selected. You are eligible to participate if you (1) have direct patient contact and (2)

meet the minimum standards of Directive 2013/55/EU amending Directive 2005/35/EC on the recognition of professional qualifications. You are invited to participate in this study, because you belong to the clinical staff of one of these departments and meet the selection criteria.

What will my participation in the study involve?

In order to participate in the survey, we ask you to register on Meplis Care Monitor after receiving your activation link. Following the instructions given in the questionnaire, we ask you to answer 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 this invitation. Once you have successfully created an account and participated in the first survey, you will receive an automatically generated mail by Meplis Care Monitor for three more times, inviting you to participate in the annual survey. If you are new to this hospital and did not participate in the last measurement occasion(s) please reach out to the person instructed by the hospital in order to invite you to the Meplis Care Monitor platform.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep. After signing up at Meplis Care Monitor, you will be asked to express your consent before completing the questionnaire. You will not be able to engage in the survey prior to providing an informed consent. If you decide to take part you are still free to withdraw at any time and without giving a reason. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Are there any benefits for me in joining the study?

You have no direct benefit from participation and will not be compensated for your participation (there are no costs or compensation associated with 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.

Are there any risks for me in joining the study?

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. However, you may feel uncomfortable reading the information and answering the questions.

Who has approved this study?

The research project was submitted to the central and/or local ethics committees within your country for approval. This authority has not raised any objections to the design of the study.

Will information about me be kept confidentially?

If you agree to participate in this study, a unique code will be stored along with your answers. Nobody but you can make the connection between your identity, this code, and your answers. Your data will be processed in accordance with Regulation (EU) 2016/679 of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, which entered into force on 25 May 2018. If the results of the study are published, your anonymity is guaranteed. The final results of the analyses will be published on the Magnet4Europe website (www.magnet4europe.eu) and will be publicly accessible. Your identity will not be revealed in any of these cases. Individual answers will not be published and also research reports will not include information on clinical staff or individual hospitals. Neither the hospital nor your superiors will have access to individual answers.

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Consent to participate in the study

	Mark 'Yes' to continue
I hereby declare that I have been informed in an understandable manner about the nature, method and purpose of this study.	Yes
I agree to participate in this scientific research.	Yes
I am aware that participation in these studies does not entail any additional costs and that there is no financial benefit.	Yes
I am aware that I can withdraw at any time up to the moment that the data is kept in the database without having to make a statement and without this in any way affecting me.	Yes
I understand that my data is collected and registered confidentially, and that the principal investigator guarantees its confidentiality.	Yes

Date	Signature

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Dear Sir/Madam,

you have been invited to take part in a research study that aims to improve mental health and wellbeing among health professionals in Europe. The project is funded under the European Union's Horizon 2020 Research and Innovation programme from 2020 to 2023 (Grant Agreement 848031). The study will be conducted in compliance with your country's ethics guidelines for scientific studies on individuals. Your participation will neither involve costs nor reimbursements. You can withdraw from the study at any time, without giving a reason. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and to decide whether you wish to take part or not. Ask us if there is anything that is not clear or if you would like to receive more information. For questions, please reach out to the Magnet4Europe project coordinator prof. dr. Walter Sermeus at walter.sermeus@kuleuven.be

What is the purpose of the study?

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 six European countries (Belgium, United Kingdom, Germany, Ireland, Norway, 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.

How does this research study work?

This research study will be carried out between January 2020 and December 2023 in adult inpatient units. The intervention itself will officially start in September 2020 in participating European hospitals and will target the five overarching principles of the Magnet® concept: structural empowerment of clinical staff, transformational leadership, exemplary and evidence-based professional practice, new knowledge, innovations, and improvements, and empirical outcomes. These principles will serve as a continuous feedback loop as to whether organizational changes are producing the intended outcomes for staff and patients. The Magnet® blueprint provides definitions of the principles and gives examples of evidence-based indicators that reflect progress toward achieving them. To facilitate the implementation process, each participating European hospital receives support by one to one twinning with an experienced Magnet recognized hospital including annual on-site visits and by the creation of a critical mass of participating hospitals drawing public interest and promoting innovation, and replication. You are asked to participate in this study because your workplace belongs to one of the hospitals participating in the Magnet4Europe project. A selection of nurses and doctors working at the participating hospitals will be asked to participate in focus groups (i.e. moderated interactive group discussions) or individual interviews. Focus groups and interviews will be used to investigate experiences and perceptions of the implementation process and to identify factors that hinder or facilitate the implementation of the intervention.

Why have I been invited and am I eligible?

60 hospitals across the six European countries being involved have agreed to participate in this study. Within each participating hospital, all adult inpatient units including ICU and ER have been selected. You are eligible to participate if you (1) have direct patient contact and (2) meet the minimum standards of Directive 2013/55/EU amending Directive 2005/35/EC on the recognition of professional qualifications.

You are invited to participate in this study, because you belong to the clinical staff of one of these departments and meet the selection criteria.

What will my participation in the study involve?

We want to investigate perceptions of the clinical work environment and to monitor the mental health and well-being of healthcare professionals among the hospitals participating in Magnet4Europe. Participation means that you will participate in a focus group discussion (i.e. together with about 2-7 other people from your hospital) or in an individual interview that will be about your experiences and experiences of the Magnet4Europe project at your workplace. The interviews and the focus group discussions are estimated to take about 30–60 minutes and 90–120 minutes respectively. The interviews and focus group discussions are conducted in person or via virtual means. The interviews and focus group discussions will be recorded through audio recording so that they can later be transcribed verbatim and analyzed.

Do I have to take part?

Your participation is voluntary and you can choose to cancel the participation at any time. If you choose not to participate or want to cancel your participation, you do not need to state why, nor will it affect your work or employment in the future. If you wish to cancel your participation, you should contact the person responsible for the study (see contact details at the end of the information letter).

Are there any benefits or risks for me to participate in the study?

You have no direct benefit from participation and will not be compensated for your participation (there are no costs or compensation associated with participation). However, we hope that your participation in the study will help us to gain more insight on how you perceive the implementation process in your hospital. By doing so, you can help to improve the working environment and safety of patient care. There are no disadvantages associated with participation. You should be aware, however, that the questions discussed during the interviews and focus groups can elicit discomfort or other emotional responses. If you feel that you need to talk to someone after the interviews, we recommend that you contact occupational health care expert at your hospital.

Will information about me be kept confidentially?

The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing any information about you to anyone outside of the research team. If you participate in a focus group discussion, we will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

Who has approved this study?

The research project was submitted to the central and/or local ethics committees within your country for approval. This authority has not raised any objections to the design of the study.

How do I get information about the results of the study?

The results of the study will be compiled at the group level and reported in such a way that no individual individuals will be able to be identified. The results of the study will be published in scientific journals and research reports in such a way that individual answers, individuals, clinics or hospitals cannot be identified. Results from the study will also be published on Magnet4Europe's website, www.magnet4europe.eu, but will not contain information that allows individuals or hospitals to be identified.

Feel free to contact us if you have any questions or if you would like more information.

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Consent to participate in the study

I have been given oral and written information about the study and have had the opportunity to ask questions. I may retain the written information.

I agree to participate in an interview or focus group discussion within the study Magnet4Europe

I agree that information about me is processed in the manner described in the research information.

Date	Signature