BMJ Open

Peer support impact on therapeutic adherence in patients with multiple sclerosis: a mixed-methods pilot trial protocol

Léonor Guilmault ,[1] Sandrine Wiertlewski,[2] Lucie Malloggi,[1] Cécilia Rousseau,[1] Marylène Jacq-Foucher,[2] Brice Leclere,[1] Leila Moret[1,3]

To cite: Guilmault L, Wiertlewski S, Malloggi L, *et al*. Peer support impact on therapeutic adherence in patients with multiple sclerosis: a mixed-methods pilot trial protocol. *BMJ Open* 2023;**13**:e071336. doi:10.1136/bmjopen-2022-071336

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-071336).

Received 24 February 2023
Accepted 14 December 2023

[1]Service de santé publique, Nantes University Hospital, Nantes, France
[2]Service de neurologie, Nantes University Hospital, Nantes, France
[3]INSERM, MethodS in Patients-Centered Outcomes and HEalth Research, SPHERE, Nantes and Tours University Hospitals, Nantes University, Tours University, Nantes, France

Correspondence to
Leila Moret;
leila.moret@chu-nantes.fr

ABSTRACT

Introduction Patient partnership is a key component of patient-centred care. One form of partnership is individual peer support, which can improve patients' quality of life and adherence to treatment. Patient with multiple sclerosis could benefit from this type of support, but such an intervention has not been explored in the literature.
We propose in this article a pilot study protocol to assess the feasibility and acceptability of healthcare-integrated individual peer support, and the feasibility of a large-scale efficacy trial.

Methods and analysis The PAIR-SEP study is a mixed-methods pilot clinical trial combining quantitative and qualitative approaches. Sixty patients with relapsing-remitting multiple sclerosis undergoing drug therapy from the Neurology centre of Nantes University Hospital (France) will be randomised on a 1:1 ratio to receive either usual care only or usual care combined with peer support (three individual sessions at 1, 3 and 5 months with a peer helper).
We will evaluate clinical outcomes in preparation of the large-scale trial: therapeutic adherence 6 months after baseline, therapeutic compliance, quality of life, anxiety and depression, social support. All dimensions will be assessed using validated health questionnaires at baseline and at 6 months.
Intervention's acceptability and feasibility will be evaluated using qualitative methods: undirected interviews with patients from the intervention group and separate focus-groups with the peer helpers the healthcare team.

Ethics and dissemination Ethical approval was obtained from the local ethics committee on 1 October 2022. This study was designed in collaboration with multiple sclerosis peer helpers.
The trial findings will be published in peer-reviewed journals.

Trial registration number NCT05519553.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The mixed-methods approach of this study will allow for an in-depth evaluation of the study objectives.
⇒ We will not only evaluate the feasibility of the larger-scale trial, but also on the feasibility and acceptability of the intervention in itself.
⇒ The qualitative and quantitative results relating to the implementation of the intervention will be useful to adapt it to a real-world setting.
⇒ As our study will only be conducted at one site, insights about the generalisability of our intervention will be limited.
⇒ As with any feasibility study, our results about multiple sclerosis patients' therapeutic adherence are exploratory and should be interpreted with a lot of care.

INTRODUCTION

With the significant increase in chronic diseases prevalence, patient partnership has gradually emerged to the detriment of the paternalistic approach.[1] The Montreal model, created by researchers of the Centre of Excellence for Partnership with Patients and the Public (CEPPP) nearly 15 years ago, describe a patient partner as 'a person progressively habilitated, during their care pathway, to make free and informed health choices. Their experiential knowledge is recognized and their self-care skills are developed with help from the healthcare team. […] They are full member of the team when it comes to the care and services offered to them'.[2 3] Thus, patients' engagement (and of their relatives) alongside healthcare workers constitute a continuum from collaboration, as coactors of their own care, to participation, using their experiential knowledge of the disease to take part in institutional decisions.[4]

One form of patient engagement is peer support, where patient partners provide guidance to other patients, helping them for example to adjust to their new way of living or to maintain or strengthen social bonds. These patient partners are generally called 'peer helpers'. Peer support interventions can take a variety of forms: moderation or comoderation of discussion groups and patient education sessions, one-to-one consultations with

patients, support before or during a medical appointment or hospitalisation, etc.

Studies exploring the clinical benefits of peer support are still scarce and usually do not provide high-level evidence of efficacy,[5–7] but their results are promising. Indeed, several qualitative studies have shown that peer support is greatly appreciated by both patients and patient partners, and that it provides patients with a feeling of hope, positivity and ways to cope with their disease.[8–12] Comparative studies have shown a significant impact of peer support on psychological outcomes (eg, depression, self-efficacy and self-management) in patients with cancer[9] and with serious mental illnesses,[6] but also on many recovery outcomes (eg, HbA1c, blood pressure and weight reduction) in patients with diabetes.[6] Large-scale studies are needed to confirm these results and evaluate their transferability to other chronic conditions.

One chronic disease in which peer support could be beneficial is multiple sclerosis (MS). In France, 5000 new cases of MS are diagnosed every year and an estimated 100 000 persons live with the disease. It is the first non-traumatic cause of disability in adults. Clinical symptoms and disease evolution can vary greatly from one patient to another, but they usually have an important negative effect on their quality of life.[13 14] As of today, there is no cure for MS and drug therapy is mostly meant to diminish relapses duration and severity and slow down the course of the disease.

As in many other chronic diseases,[15] MS patients' adherence to their long-term treatment is low and therapeutic compliance estimates vary between 40% and 88% depending on the studies.[16] Non-compliance seems to exacerbate the frequency and severity of relapses, the importance of cognitive impairment and the progression of disabilities.[17 18] Numerous factors have been shown to increase non-compliance: belief of ineffectiveness, missed doses, side-effects, fear of injections, all of which could be addressed via peer support.[19] Indeed, by sharing their experiences and resources, and providing support and information, peer helpers could have a positive influence on patients' disease-related representations and treatment beliefs, which are key determinants of treatment adherence and compliance. However, to our knowledge, no research has been conducted on the impact of peer support on MS patients.

In order to successfully conduct such studies, several implementation barriers have to be lifted. Indeed, in this type of one-to-one partnership, the necessary sharing of knowledge and power represents a real paradigm shift for healthcare professionals, which could be difficult to accept. On the one hand, they must be able to adapt their posture to consider patients as fully-fledged members of the care team; on the other hand, it is essential that each actor's roles and responsibilities are clearly defined beforehand. A preliminary work seems therefore essential.

In this article, we present the protocol of a pilot trial that aims to address these issues. The goals of this study are twofold: (1) to explore the feasibility and acceptability of peer support interventions among peer helpers and healthcare workers and (2) to evaluate several clinical and psychological outcomes (therapeutic adherence, quality of life, emotional state and social support) that could be useful for a large-scaled trial.

METHODS AND ANALYSIS

This article follows the 2013 Standard Protocol Items: Recommendations for Interventional Trials and 2010 Consolidated Standards of Reporting Trials (CONSORT) statements, for reporting trial protocols and pilot trials, respectively.[20] The WHO Trial Registration Data Set was also completed (see online supplemental material 1).

Study design

The PAIR-SEP study is a mixed-methods pilot trial with a convergent design: quantitative and qualitative data will be collected, analysed and compared with answer the pursued objectives.

The qualitative study will be based on individual and group interviews of patients, peer helpers and healthcare workers. The quantitative study will consist of an open-label randomised controlled pilot trial with two parallel groups: a control group receiving usual care only, and an intervention group receiving usual care combined with three peer support interviews (set at 1, 3 and 5 months after inclusion).

The study will consist of three parts:

1. Intervention planning, consisting in the recruitment and training of a small group of MS patients (n=3) who will act as peer helpers, and in the cocreation of an interview grid for the three peer support sessions.
2. Trial implementation, with the conduction of peer support interventions for the intervention group.
3. Qualitative investigation, consisting of undirected interviews for patients and focus groups for peer helpers and professionals.

The inclusion period will last 9 months (beginning in June 2023) and participants will be followed up during 6 months. The overall data collection lasts 15 months.

Study setting

The study will take place at Nantes University Hospital (France), in which a project to structure patient partnership is underway. This project is based on the experience of several clinical departments working informally with patient partners. For several years now, the neurology department has been collaborating with a volunteer patient–partner from the French League against MS to run a discussion group with MS patients on the ward. The presence of a psychologist and an advance practice nurse in the department has helped to improve quality of care with a more holistic perspective of the disease.

Eligibility criteria

This study is focused on adult MS patients whose care is managed by the Neurology Department of Nantes Hospital. The following profiles will be included:

- Adult patients
- With relapsing-remitting MS according to 2017 revised Mc Donald criteria[21] (more than 80% of MS patients),
- Attending medical consultation at Nantes University Hospital Neurology Department,
- For whom background drug therapy is needed (oral or injectable),
- Who gave consent to participate in trial.

The exclusion criteria are as follows:

- Primary-progressive or secondary-progressive MS patients
- Patients under protection of vulnerable adult's measure or convicted
- Patients not fluent in French
- Patients with severe cognitive impairment, who may find difficult filling out questionnaires properly
- Patients prone to follow-up interruption (home moving, nomadism…)

Outcomes

The outcomes will relate to our two objectives: peer support impact on MS patients and feasibility/acceptability of the study.

Peer support impact

As PAIR-SEP is a pilot study, all impact outcomes are exploratory and are therefore on the same level, however therapeutic adherence was chosen as primary for the sake of the sample size calculation. These preliminary results will be used to inform the protocol of a future multicentre randomised controlled trial. All impact outcomes will be assessed using difference in questionnaire scores between baseline and 6 months in both groups.

Therapeutic adherence will be explored using the mean score difference at baseline and after 6 months of the 'Necessity' and 'Concerns' subscales of the BMQ (Beliefs about Medicines Questionnaire) Specific scale. The BMQ has been validated as a screening test for low therapeutic adherence in several chronic diseases[22 23] and has recently been used in MS patients.[24 25] This questionnaire consists of two scales, BMQ-General and BMQ-Specific, which can be used separately. The BMQ-Specific scale assesses treatment-associated beliefs, according to 10 items and two subscales: treatment necessity and treatment concerns. The items are scored on a 5-point Likert scale ranging from 'Totally agree' (one point) to 'Totally disagree' (five points). A final score, ranging between 5 and 25, is calculated for each subscale by summing the answers to each item. The psychometric properties of this scale have been validated in several populations, mostly chronic patients (asthma, renal failure, psychiatric pathologies, …).[23 26] Cronbach's alpha coefficients of the Specific-Necessity and Specific-Concerns subscales range, respectively, from 0.55 to 0.86 and from 0.63 to 0.80 depending on the population studied.[23] A validated French version, published by Fall *et al*, in 2014 is available.[27]

According to the Necessity-Concerns framework (NCF), the score of the Concerns subscale can be subtracted to the score of the Necessity subscale to compute an indicator called the NCF. The NCF varies between −20 and +20, and a positive value indicates that the perceived treatment necessity exceeds treatment associated concerns. The closer the NCF comes to +20, the better risk/benefit balance of the treatment is. Several studies have showed that patients with a higher perceived treatment necessity or lower treatment associated concerns (as assessed by BMQ-Specific) are more prone to follow their physician's recommendations.[25 28 29]

Therapeutic compliance will be assessed by the mean score difference at baseline and after 6 months of the Medication Adherence Rating Scale (MARS) questionnaire. MARS is a validated tool to assess therapeutic compliance in chronically ill patients.[30 31] The short version consists of 5 items, scored on a Likert scale ranging from 1 to 5. A final score, between 5 and 25, is calculated by summing the answers to the items. If the final score is 21 or above, or if every item is scored at least four points, the patient is deemed compliant. The MARS questionnaire was adapted and validated in French by Misdrahi *et al* in 2004[32] and then by Fond *et al* in 2017.[31]

Quality of life will be assessed by the mean score difference at baseline and after 6 months of the MusiQoL-MCAT. This short questionnaire was specifically designed for MS patients, with a validated French translation and good psychometric properties.[33 34] It consists of 31 items, divided in nine dimensions: activities of daily living (eight items), psychological well-being (four items), symptoms (four items), relationships with friends (three items), relationships with family (three items), relationships with healthcare system (three items), sentimental and sexual life (two items), coping (two items), and rejection (two items). Each item is scored on a 6-point Likert scale, ranging from 'never/not at all' (one point), to 'always/very much' (five points) with an extra value for 'not applicable' (six points). For each individual, the score for each dimension is obtained by computing the average score of the related items. All dimension scores are linearly transformed to a 0 to 100 scale and an overall average score is computed. Higher scores indicate a higher level of quality of life.

Emotional well-being will be assessed using the mean score difference at baseline and after 6 months of the HAD (Hospital Anxiety and Depression) questionnaire. The HAD scale allows for anxiety and depressive disorders screening.[35] It consists of two subscales (anxiety and depression) of seven items each. The possible score for each item ranges from 0 to 3, and a subscale score superior to eight denotes anxiety or depression. The higher the score is, the higher the severity of the symptoms. The HAD questionnaire was created in 1983 and was used in several chronic diseases, including MS.[36 37] Its French

translation was made by Lépine *et al* and validated by Ravazi *et al* in 1989.[38 39]

Social support will be assessed using the mean score difference at baseline and after 6 months of the 6-item Social Support Questionnaire (SSQ6). Social support can be assessed in two ways: objective (received social support) or subjective (perceived social support). Perceived social support refers to how individuals perceive friends, family members and others as sources available to provide material, psychological and overall support during times of need. Studies on peer support impact on chronic patients show that one of the main benefit of peer support is on perceived social support.[10 11 40]

SSQ6 is a 6-item questionnaire designed to measure perceived social support using two dimensions: satisfaction and availability of support. This questionnaire is a shortened version of the original Social Support Questionnaire designed by Sarason *et al* in 1983.[41] It has been translated and validated in French.[42] Each item is a question that solicits a two-part answer: part 1 asks participants to list from 0 to 6 people that fit the description of the question, and part 2 asks participants to indicate how satisfied they are with the support provided by each of these people, using a 6-point Likert scale (6: 'very satisfied' to 1: 'very dissatisfied'). Two scores are then calculated by summing the answers within each dimension: The N score (availability) ranges from 0 to 54 and the S score (satisfaction) ranges from 6 to 36.

Study feasibility and acceptability

An important part of the study is to explore what participants, healthcare team and peer helpers think of the peer support interventions that will take place. It seems essential to assess the strengths and weaknesses of the study to make consistent change and improve the method with a broad-scale implementation perspective. Thus, qualitative data will be collected, using undirected individual interviews with the participants of the intervention group and focus-groups dedicated to collect feedback from peer helpers and the Neurology Department healthcare team.

Intervention group patients' interviews

The possibility to participate in an undirected interview will be given to each patient in the intervention group at the end of the quantitative assessment. This interview will be conducted by a member of the research team and is estimated to last for about an hour. It will explore how the patient felt during peer support sessions, what it meant to them to receive guidance and advice, if it changed their disease representations or daily experience. It will allow for an overview of all MS patients' life dimensions affected by the peer support interventions. The interviews will also give the opportunity to know what MS patients expected from peer support and what they actually got from it, giving leads on how to improve the programme.

Focus groups

Two separate focus groups will be organised to better understand what the study entailed for the healthcare team and peer helpers.

A focus group with only peer helpers will allow the exploration of several aspects of the study: recruitment, training, coaching during intervention, study organisation and unfolding, drivers and barriers to participate in the study as a chronic patient themselves. Peer helper's feedbacks will be crucial to improve the programme, as peer support interventions have to be tailored to the needs of not only MS patients but also peer helpers, as they also experience physical and psychological consequences of the disease.

Another focus group will be organised with the healthcare professionals of the hospital's Neurology Department. Their feedback on the conduct of the study will be collected, exploring themes such as the introduction of the peer helpers to the team, teamwork with peer helpers, work relationship between healthcare team and peer helpers, study impact on the team and study endorsement. A good relationship between peer helpers and the Neurology healthcare team is essential, as malfunctions could jeopardise the study.

Interventions

The study is designed in three parts: intervention planning, intervention and evaluation. The PAIR-SEP research team consists in a peer helper, a neurologist, an advanced practice nurse, two public health physicians, a quantitative methodologist and two qualitative methodologists.

Intervention planning

At the time of writing this article, the recruitment of the peer helpers has already taken place. The objective was to constitute a group of three MS patients able to provide support to patients in the intervention group. The principal investigator (neurologist specialised in MS) identified several patients in her clientele to whom she offered to participate as a peer helper in the study. The first one is the patient who already runs the discussion groups and helped to set up the research project. The other two patients are women who have expressed their willingness to become patient partners. They were involved in patient associations prior to their recruitment. All of them agreed to take part in the research and signed a contract as temporary hospital collaborators.

The peer support team has been introduced to the Neurology Department staff (nurses, psychologist, other physicians, etc) before the start of the inclusion to create a positive work atmosphere. To better explain their missions, a flyer presenting the objectives of the study and entitled 'Who better than a patient to understand what life with multiple sclerosis is like on a daily basis?' was created with the three peer-helpers. In the flyer, each of them introduces themselves and briefly explains their experience with MS. This flyer will be distributed to every patient interested to participate in the project.

A specific training has been offered to the three peer helpers. First, the research team explained them the study's objectives and anticipated course of events. Second, to prepare peer helpers for their coaching role, a specific training has been organised by an engineer specialised in pedagogy and therapeutic education, working at the Public Health Department of the hospital and involved in the research. Based on the CEPPP's patient partner recruitment guide,[43] we created a self-assessment questionnaire that was filled in by each of the three peer helpers. This questionnaire was used to assess the peer helpers' skills in several domains: communication, empathy, listening and coping with chronic illness. The training was developed according to the three patients' answers and focused on what they needed most to feel comfortable as a peer support coach.

The three peer helpers were then involved in creating the interview guides. These grids will serve as guidelines to lead each interview, summarising objectives and themes according to the stage of intervention (first, second or third interview), in order to ensure some homogeneity in the conduct of the intervention between patient and peer helper.

Since recruitment, the peer helpers were involved in supplementary training sessions (role-playing) conducted each month by the pedagogy engineer and a public health physician.

Intervention

The intervention in itself will consist of three individual sessions between a peer helper and a patient. The first session will systematically take place on hospital grounds, but the two following sessions can be organised according to the patient's preferences either via videoconference or in person at the hospital. These sessions will each be approximately 1 hour long and will consist in a discussion between the patient and the peer helper, centred on the patient's disease experience and the difficulties associated with it in daily life, relating notably to treatment adherence, quality of life, social support and symptoms. Each patient will meet the same peer helper at every session, in order to create a bond and facilitate communication. At the end of every meeting, the peer helper will fill out a follow-up sheet and a summary will be written at the end of the three sessions, that will be incorporated in the patient file. This synthesis will be used as a basis for a meeting between the peer helper and the Neurology Department advanced practice nurse, where the effect of the intervention on the patient will be discussed.

During the entire intervention phase, coaching will be available to peer helper in the form of psychological support if needed from the Neurology Department. The peer helpers will also be able to seek help or advice from the research team.

Evaluation

At baseline, patients from both groups will fill out a questionnaire during the inclusion visit, using the Wepi software from Epiconcept. The same questionnaire will be filled out online by patients from both groups, 6 months after inclusion, via a link sent by email. The questionnaire will assess five dimensions: therapeutic adherence (specific BMQ), therapeutic compliance (MARS), quality of life (MusiQoL-MCAT), anxiety and depression (HAD) and social support (SSQ6).

Patients from the intervention group will be asked to participate in an optional undirected interview with a member of the search team after the final questionnaire and two focus-groups will be organised (one with the peer helpers, the other with the Neurology Department team).

Participant timeline

The study will be presented to each potential participant during a check-up medical consultation at the Neurology Department. If the patient is interested, he will receive an information letter detailing the research objectives and course of actions. A reflection time of 1 week will be provided to let the patient decide if he wants to be part of the study. He will then be contacted by the research team to schedule an inclusion meeting if he is interested.

The inclusion meeting will consist of four steps: (1) checking eligibility, (2) patient inclusion and written consent, (3) baseline questionnaires and (4) randomisation. Randomisation will be implemented by the Neurology Department clinical research team without stratification, using a randomisation list included into the Clinical Ennov software. The randomisation list was constructed by a statistician using blocks of random sizes (2–4), with a 1:1 ratio. The result (experimental or control group) will be sent via an automatic email to the investigators and peer helpers. One peer helper will be assigned to each patient randomised in the intervention group, according to the peer support team planning and the patient's availabilities to schedule meetings.

If the patient is randomised in the control group, usual care will be followed through. If the patient is randomised in the intervention group, the research team will inform them that a peer helper will get in touch with them via email (or phone) to schedule the first meeting.

At the end of inclusion meeting, a 1 week period will be chosen 6 months after baseline for the patient to fill out the final questionnaires. If needed, an assistance to fill out the questionnaires will be given by the search team, either via phone or face to face on hospital grounds.

The patients from the intervention will then benefit from the intervention, whereas the control group will receive usual care. Both groups will fill out questionnaires at baseline and after 6 months, as described above.

Sample size

For this pilot study, we plan on recruiting 60 patients (30 in control group and 30 in intervention group) for a first evaluation on therapeutic adherence with enough precision. This number is coherent with Whitehead *et al* suggestions[44] to enrol at least 25 patients in each arm in a pilot study for a small-range standardised effect (20%).

By postulating a mean of 13.6 and a SD of 3.6 on every subscale of the BMQ (hypothesis made from the study by Kooy *et al* in 2015[45]), our sample will allow for mean score on each subscale with a precision of $2\times1.96\times(\frac{3,6}{\sqrt{30}}) = 2.58$, which is around 19% of the mean.

Data collection and management

To enhance participants' retention, email reminders will be sent before each peer support session and before the final questionnaire. Data management will be conducted with data quality promotion in mind.

No data monitoring committee has been implemented for this study as the sample is very limited in size. No interim analyses or stopping guidelines will be necessary. Trial conduct will be supervised by the research committee in monthly meetings, under the supervision of the investigators but without interference from the sponsor.

Data analysis plan

In this a mixed-methods study, data analysis will depend on the nature of the data: quantitative or qualitative.

Quantitative data

Descriptive analysis

The distribution of the variables will be described using means, medians, SD and ranges for quantitative variables and with total numbers and proportions of each modality for qualitative variables.

The main results will consist in the difference between the score at baseline and after 6 months of the following scales: therapeutic adherence (BMQ-Specific), therapeutic compliance (MARS), anxiety and depression (HAD), social support (SSQ6) and quality of life (MusiQoL-MCAT).

In accordance to the CONSORT guidelines for pilot and feasibility studies, the difference between the two groups will only be indicative, and no formal statistical testing will be performed. Data analysis will be performed on complete observations; no missing data imputation will be used.

Qualitative data

Data from the two focus-groups and MS patients' interviews will be analysed using the same process.

A thematic analysis using conceptual categories will be performed. After a phenomenological examination of data, followed by an open coding phase, axial coding will allow for a pooling of meaning units in conceptual categories. Memo writing and frequent back and forth between categories, synthesis and raw data will guaranty theorisation integration in patients' experience.

To neutralise any possible interpretative biases, a triangulation will be implemented, by submitting data to two analysts in order to compare in a critical way their interpretations.

If necessary, the analyses will be performed using a qualitative analysis software.

Patient and public involvement

A MS peer helper is part of the scientific committee of this study and involved in designing and implementing the study.

Ethics and dissemination

The local institutional review board 'Groupe Nantais d'Éthique dans le Domaine de la Santé' approved this study on 1 October 2022. All participants will provide written consent during the inclusion visit with the neurologist in charge of the trial (see online supplemental material 2).

The trial results are expected in 2024. These findings will be submitted and published in international peer-reviewed journals in 2025.

Any important protocol modifications will be communicated to relevant parties via email. All personal information about potential and enrolled participants will be kept confidential, using pseudonymisation on data before analysis. All final trial data set will be accessible to member of the research team who will proceed with analysis.

Acknowledgements We would like to sincerely thank Maxime Lebeaupin and every patient adviser for their time and dedication to this study.

Contributors All authors were involved in the study design, and they all read and approved the final manuscript. LG contributed to conception and design of this study, drafted the manuscript and reviewed and revised the manuscript. SW contributed to conception and design of this study, selection of peer helpers, recruitment of patients and manuscript proofreading. LMa and MJ-F contributed to conception and design of this study, manuscript proofreading. CR contributed to conception and design of this study, manuscript proofreading. BL and LMo contributed to conception and design of this study, manuscript proofreading, revision of the manuscript.

Funding This work was supported by CHU Nantes, France. As a non-commercial sponsor, it had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data or decision to submit results. Trial Sponsor: CHU Nantes.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

ORCID iD

Léonor Guilmault http://orcid.org/0000-0002-4334-7157

REFERENCES

1 Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *N Engl J Med* 2012;366:780–1.
2 Carman KL, Dardess P, Maurer M, *et al*. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. *Health Affairs* 2013;32:223–31.
3 Karazivan P, Dumez V, Flora L, *et al*. The patient-as-partner approach in health care: a conceptual framework for a necessary transition. *Acad Med* 2015;90:437–41.
4 Pomey MP, Flora L, Karazivan P, *et al*. The Montreal model: the challenges of a partnership relationship between patients and healthcare professionals. *Sante Publique Vandoeuvre--Nancy Fr* 2015;27(1 Suppl):S41–50.
5 Dale JR, Williams SM, Bowyer V. What is the effect of peer support on diabetes outcomes in adults? A systematic review. *Diabet Med* 2012;29:1361–77.
6 Chinman M, George P, Dougherty RH, *et al*. Peer support services for individuals with serious mental illnesses: assessing the evidence. *PS* 2014;65:429–41.
7 Baik SH, Gallo LC, Wells KJ. Patient navigation in breast cancer treatment and survivorship: A systematic review. *JCO* 2016;34:3686–96.
8 Vigneault K, Higgins J, Pomey M-P, *et al*. Bringing patient advisors to the bedside: a promising Avenue for improving partnership between patients and their care team. *Patient Experience Journal* 2015;2:16–22.
9 Meyer A, Coroiu A, Korner A. One-to-one peer support in cancer care: a review of scholarship published between 2007 and 2014. *Eur J Cancer Care (Engl)* 2015;24:299–312.
10 Nicks SE, Wray RJ, Peavler O, *et al*. Examining peer support and survivorship for African American women with breast cancer. *Psychooncology* 2019;28:358–64.
11 Skirbekk H, Korsvold L, Finset A. To support and to be supported. A qualitative study of peer support centres in cancer care in Norway. *Patient Educ Couns* 2018;101:711–6.
12 St-Pierre D, Bouchard K, Gauthier L, *et al*. Perspectives of women considering bilateral prophylactic mastectomy and their peers towards a telephone-based peer support intervention. *J Genet Couns* 2018;27:274–88.
13 Kidd T, Carey N, Mold F, *et al*. A systematic review of the effectiveness of self-management interventions in people with multiple sclerosis at improving depression, anxiety and quality of life. *PLoS One* 2017;12:e0185931.
14 Patten SB, Beck CA, Williams JVA, *et al*. Major depression in multiple sclerosis: a population-based perspective. *Neurology* 2003;61:1524–7.
15 Burkhart PV, Sabaté E. Adherence to long-term therapies: evidence for action. *J of Nursing Scholarship* 2003;35:207.
16 Menzin J, Caon C, Nichols C, *et al*. Narrative review of the literature on adherence to disease-modifying therapies among patients with multiple sclerosis. *JMCP* 2013;19(1 Supp A):S24–40.
17 Steinberg SC, Faris RJ, Chang CF, *et al*. Impact of adherence to Interferons in the treatment of multiple sclerosis: a non-experimental, retrospective, cohort study. *Clin Drug Investig* 2010;30:89–100.
18 Tan H, Cai Q, Agarwal S, *et al*. Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis. *Adv Ther* 2011;28:51–61.
19 Schoor R, Bruce A, Bruce J, *et al*. Reasons for Nonadherence and response to treatment in an adherence intervention trial for relapsing-remitting multiple sclerosis patients. *J Clin Psychol* 2019;75:380–91.
20 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
21 Thompson AJ, Banwell BL, Barkhof F, *et al*. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol* 2018;17:162–73.
22 Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication. *Psychology & Health* 1999;14:1–24.
23 Arıkan H, Duman D, Kargın F, *et al*. Cross-cultural adaptation and validation of beliefs about medicines questionnaire on asthma and chronic obstructive pulmonary disease patients. *Turk Thorac J* 2018;19:36–40.
24 Pust GEA, Untiedt B, Weierstall-Pust R, *et al*. Medication beliefs in first-line and second-line treated multiple sclerosis patients. *Mult Scler Relat Disord* 2020;42:102144.
25 Thach AV, Brown CM, Herrera V, *et al*. Associations between treatment satisfaction, medication beliefs, and adherence to disease-modifying therapies in patients with multiple sclerosis. *Int J MS Care* 2018;20:251–9.
26 Wei L, Champman S, Li X, *et al*. Beliefs about medicines and non-adherence in patients with stroke, diabetes mellitus and rheumatoid arthritis: a cross-sectional study in China. *BMJ Open* 2017;7:e017293.
27 Fall E, Gauchet A, Izaute M, *et al*. Validation of the French version of the beliefs about medicines questionnaire (BMQ) among diabetes and HIV patients. *European Review of Applied Psychology* 2014;64:335–43.
28 Horne R, Weinman J. Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *J Psychosom Res* 1999;47:555–67.
29 Cea-Calvo L, Marín-Jiménez I, de Toro J, *et al*. Association between non-adherence behaviors, patients' experience with Healthcare and beliefs in medications: a survey of patients with different chronic conditions. *Curr Med Res Opin* 2020;36:293–300.
30 Thompson K, Kulkarni J, Sergejew AA. Reliability and validity of a new medication adherence rating scale (MARS) for the psychoses. *Schizophr Res* 2000;42:241–7.
31 Fond G, Boyer L, Boucekine M, *et al*. Validation study of the medication adherence rating scale. results from the FACE-SZ national Dataset. *Schizophr Res* 2017;182:84–9.
32 Misdrahi D, Verdoux H, Llorca PM, *et al*. Therapeutic adherence and schizophrenia: the interest of the validation of the French translation of medication adherence rating scale (MARS. *Encephale* 2004;30:409–10.
33 Simeoni M, Auquier P, Fernandez O, *et al*. Validation of the multiple sclerosis International quality of life questionnaire. *Mult Scler* 2008;14:219–30.
34 Baumstarck K, Butzkueven H, Fernández O, *et al*. Responsiveness of the multiple sclerosis International quality of life questionnaire to disability change: a longitudinal study. *Health Qual Life Outcomes* 2013;11:127.
35 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
36 Honarmand K, Feinstein A. Validation of the hospital anxiety and depression scale for use with multiple sclerosis patients. *Mult Scler* 2009;15:1518–24.
37 Pais-Ribeiro JL, Martins da Silva A, Vilhena E, *et al*. The hospital anxiety and depression scale, in patients with multiple sclerosis. *Neuropsychiatr Dis Treat* 2018;14:3193–7.
38 Lépine JP, Godchau M, Brun P, *et al*. Évaluation de L'Anxiété et de la Dépression Chez des patients Hospitalisés Dans UN service de Médecine interne anxiety and depression evaluation in patients hospitalized in an internal medicine unit. *Ann Méd-Psychol* 1985;143:175–89.
39 Razavi D, Delvaux N, Farvacques C, *et al*. Validation of the French version of the hospital anxiety and depression scale (HADS) in a population of hospitalized cancer patients. *Rev Psychol Appliquée* 1989;39:295–307.
40 Hoey LM, Ieropoli SC, White VM, *et al*. Systematic review of peer-support programs for people with cancer. *Patient Educ Couns* 2008;70:315–37.
41 Sarason IG, Levine HM, Basham RB, *et al*. Assessing social support: the social support questionnaire. *Journal of Personality and Social Psychology* 1983;44:127–39.
42 Bruchon-Schweitzer M, Rascle N, Cousson-Gélie F, *et al*. Le questionnaire de Soutien social de Sarason (Ssq6). une adaptation Française. *Psychol Fr* 2003;48:41–53.
43 Dumez V, Lebel P. Guide Pratique: Recrutement des patients Partenaires. *Université de Montréal* 2016.
44 Whitehead AL, Julious SA, Cooper CL, *et al*. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res* 2016;25:1057–73.
45 Kooy MJ, Van Geffen ECG, Heerdink ER, *et al*. Patients' general satisfaction with telephone counseling by pharmacists and effects on satisfaction with information and beliefs about medicines: results from a cluster randomized trial. *Patient Educ Couns* 2015;98:797–804.