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Title page

Manuscript title: Developing evidence-based patient focused learning materials to support health behaviour change for people living with psoriatic arthritis.

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Abstract

Objectives

In psoriatic arthritis (PsA) self-management is important for patient function and quality of life. Behaviour change can be difficult, patients could benefit from high-quality support to initiate change. Our aim was to co-design the project as theory informed, evidence-based, patient-focused, materials supporting healthy lifestyle changes for patients diagnosed with PsA.

Methods

Development of the materials was overseen by a steering group of patients with PsA, psychologists, rheumatologists, a design team and researchers. Firstly, a literature review was performed to establish the evidence-base for behaviours and potential interventions in PsA; including diet, weight, alcohol, smoking, exercise, anxiety, depression, and stress. An initial roundtable of patients with PsA prioritised areas and content ideas.

Draft materials including a website and downloadable materials were produced. A second roundtable of patients with PsA collected feedback on the draft content and design. A third roundtable was held with patients with PsA and a fourth with clinicians to refine the materials and ensuring they were evidence based, accessible, interesting, and helpful to initiate and maintain change. A final evaluation survey was performed to review the draft website before launching the final materials.

Results

15 candidate topics were prioritised. A website and set of postcards summarising the topics were developed by the design team and refined following feedback from the roundtable groups.

Conclusion

This project created patient-focused resources to support behaviour change. It addresses common concerns of patients with PsA about how they may optimise their health by providing practical and brief interventions to challenge and support them to make changes.

Key messages

- **What is already known on this topic**
There is a lack of evidence to support how best to manage the psychological and physical concerns of patients living with PsA.
- **What this study adds**
This project created patient focused materials and a website designed for use in clinical practice. They address the common concerns of patients living with PsA and provide information about how they may be able to optimise their health by utilising these practical and brief interventions to challenge them to make personal change/s.
- **How this study might affect research, practice or policy**
Future research is needed to test the impact of the resource.

Main manuscript

Introduction

Around three percent of the population will develop psoriasis, the inflammatory skin condition (1). Some 15 - 30% of people with psoriasis will develop psoriatic arthritis (PsA) (2). PsA can present with a range of signs and symptoms, including assorted musculoskeletal manifestations. PsA is associated with other conditions that can have a negative impact on quality of life, including depression, metabolic syndrome, and increased cardiovascular disease risk (3-5). In addition, patients living with (PsA) are at greater risk of being overweight, sedentary consuming alcohol above recommended levels, smoking, reporting poor sleep, fatigue and anxiety (6, 7). Without modification (and they may be modifiable) these health behaviours further increase cardiovascular morbidity and mortality risk (3-5).

Given the complexity of PsA it is critical that those living with it are supported to self-manage. Self-management aims to empower and enhance peoples' well-being. It puts an emphasis on sharing the responsibility for management of a condition between healthcare professionals and the individual. Supporting people to self-manage enables people with long-term conditions to live well and can reduce peoples' need for using health services (8).

Our understanding about how patients who live with PsA manage and cope with their condition remains limited (9) and evidence of how best to support and manage the psychological and physical concerns of patients living with PsA is lacking. Osborne et al, proposed that self-management is most effective when closely aligned to clinical practice. (10). For patients living with PsA, such management where possible should strongly involve the combination of the patient, the patient's PsA healthcare team, the patients' families, friends (11). The evidence-base for effective health-care professional led interventions to change behaviour is extremely limited. However, there is evidence that behaviour change interventions can support non-pharmacological management for other types of arthritis and improve outcomes (12, 13).

We aimed to identify what was already known about the health behaviours of patients living with PsA and used behaviour change theories, literature, and expert insight to develop resources to support patients living with PsA and their clinicians to encourage change. The learning resources created were developed with patients living with PsA, clinicians, researchers and psychologists, and designed to be distributed to clinicians and patients to address these lifestyle issues. In the absence of a strong evidence base for health-care professional led interventions to change behaviour in PsA, evidence-based self-management strategies were utilised from other long-term conditions. For example, motivational interviewing techniques for improving outcomes in long-term conditions including, physical activity, reducing alcohol use and weight loss (14-17).

Methods

Our process followed six steps; these are illustrated in Figure 1. The development of the materials was overseen by a steering group of patients living with PsA, psychologists, rheumatologists, and researchers in the UK who also formed the author group (LHH, LMH, CB, SK, SM, DO, IS, MS, LCC). There was wider stakeholder involvement from public contributors living with PsA and clinicians at various stages of design. The steering group chair (LCC) oversaw the process to ensure accountability and transparency. The steering

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group ran as a collaborative effort between the patients with a lived experience of the disease and those who care for them.

Scope

The planned scope of the project was adult PsA. It did not extend into PsA in childhood as this is commonly considered as a subtype within juvenile idiopathic arthritis and children may have different needs than adults.

User involvement

Patient involvement was central to the project. From the design, through all stages, to conclusion. Involvement of people affected by PsA was key to ensuring the relevance and quality of project. Steering group, Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) patient research partners included those with lived experience of PsA (DO, IS). Patient and Public contributors involved in the roundtable groups were recruited through the GRAPPA network and patient support groups, as well as social media and snowballing through these groups. Three of the four roundtables and the final evaluation survey included design input from patients with lived experience of PsA. Patient and public involvement in the project followed good practice based, upon guidance from the UK Standards for Public Involvement and National Institute for Healthcare Research. For example, for payments and recognition of involvement (18, 19). Clinicians directly involved in PsA care were recruited through specialist interest groups for health professionals and the GRAPPA Network/British Psoriatic Arthritis Consortium (Brit-PACT).

Project methods:

Step 1: Literature review

A review of the literature examined the evidence for the current burden of diet, weight, alcohol, smoking, exercise, anxiety, depression, and stress in PsA. The review also aimed to identify evidence for any interventions and the success of these (e.g. weight loss in patients with stable PsA). All members of the steering group including the patient research partners were involved in identifying topics and relevant search terms for each topic.

Step 2: Engagement forum

A patient engagement forum established priorities for the project. In December 2020 an initial roundtable group of patients living with PsA was led by steering group members (LCC, LHH, LMH, CB) to identify priority behaviours and ideas for content. LMH and CB welcomed the patients to the group and used their experience as psychologists to create a safe space for patients to feel comfortable to discuss and disclose their experiences and opinions on the topics. This enabled the patients to feel as comfortable as possible when discussing potentially sensitive issues such as intimacy. The patients were reassured they only needed to share their views on what they felt happy disclosing. DOS and IS observed the groups. The literature review results were presented. The contributors were then asked to provide feedback and insight into the topics they felt were most important, suggest any additional missing topics, and help generate ideas around the information they would hope to see included in the final materials.

Step 3: Development of content

The psychologists (CB, LMH) designed the materials to be compatible with the motivational interviewing stages and used the COM-B model to articulate how the intervention design

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targeted the three drivers of behaviour: capability, opportunity and motivation. Table 1. provides a summary of the psychologically informed design features used (20-22).

Step 4: Resource design

The steering group partnered with a design agency to translate the information and topics into engaging materials using good health literacy principles. The design team created a draft website and downloadable postcards. In June 2021 a second roundtable group comprising PsA patients was setup. This enabled the patients to provide their views on the draft content of the materials including the design, website name/logo and layout of the resources and website. The steering group refined their work based on same.

Step 5: User feedback

Following the design and production of the materials there was a two-stage evaluation, from two round table group interviews and surveys, conducted by steering group members MS and SM. Between July 2021 and August 2021, two separate group interviews/focus groups were conducted with patients living with PsA and clinicians using qualitative interview methods to evaluate the materials and ensure they were accessible, interesting, and helpful to initiate and maintain change. Participants were paid for their time to review static elements of the website prototype, and discuss questions about the proposed website in a group interview. Critical feedback from each group was used to refine the final materials and website where possible.

The user feedback survey was then performed to review the functional website prototype before launch. It ran for six weeks from 12th January 2022. Two paid surveys were developed on the platform Qualtrics – one for clinicians who work with patients living with PsA and one for patients living with PsA. The survey used scale/rank questions, followed by open ended questions to determine usability, acceptability of design and content, with questions asking about recommendation to a friend/family, and whether they were considering making health behaviour changes after looking at the resource. It included both positives/benefits and any major barriers/challenges to use that could also inform future research.

Step 6: Dissemination

To ensure the outputs from the project got to the people who need to make use of them (patients, public members and healthcare professionals) as quickly as possible and to maximise the benefits of the new resources the steering group worked closely with patient and clinician groups to promote them. A launch campaign was created and used by the groups involved on social media.

Results

Literature review

The literature review to inform the outputs of this project combined a number of different phases. An initial literature search, combining terms for patient behaviours or lifestyle and psoriatic arthritis and focused on retrieving systematic reviews, was conducted in MEDLINE (via OVID) on 17 November 2020. The purpose of this search was to inform the initial topics list that was discussed during the focus groups held in December 2020. A copy of the search strategy can be found in Supplementary Table S1. Following the focus groups, and building on the initial MEDLINE search strategy, revised and expanded search strategies were

developed (not restricted by publication type) and were run in the Cochrane Central Register of Controlled Trials (CENTRAL) (via Cochrane Library, Wiley), CINAHL (via EBSCOhost), AMED (via OVID), EMBASE (via OVID), Global Health (via OVID), MEDLINE (via OVID), PsycINFO (via OVID) on the 28 May 2021. The search results from the 17 November 2020 and the 28 May 2021, combined with the use of backward citation searching of identified references and known references obtained from experts in the steering group all informed the development of the project materials. Where guideline or systematic review level evidence was not available for a topic, the best available evidence identified was utilised along with expert knowledge. A copy of the search strategies for all the databases searched on the 28 May 2021 can also be found in Supplementary Table S1.

Engagement forum

Table 2. details the concept development roundtable groups that were conducted. The PsA groups comprised of a mix of age groups; backgrounds and stages of PsA. These discussions probed for increased understanding, acceptability, and views on the value of these new materials as part of self-management and as part of high-quality clinical care. Also, suggestions were given on the topic, content for materials, naming the website and the types of materials (for example, postcards). Suggestions for topics from the focus groups were added to the literature review. Following the steering group and roundtable input, 15 candidate topics were prioritised. The topics emerging from the roundtable groups are listed in Table 3. A draft website and downloadable postcards summarising each of the topics was developed by the design team and refined following feedback from the roundtable groups and steering group. The website developed as part of the resources is called 'informatree'. Figure 2. shows an example of how the topics are represented on the informatree website.

User feedback

Table 2. details the user evaluation roundtable groups. Key messages from the evaluation group interviews with clinicians and patients living with PsA included suggested changes to the design, colours and functionality of informatree, as well as specific feedback on the content of topics. For example, suggestions included changes to the language on the smoking and pain topics – with participants highlighting the important of rest, and an empathetic tone. It was felt that the information on informatree had a basic level of information and could be useful for those newly diagnosed. Feedback included suggested improvements on the design, colours and wording on the resource. An example of the postcard for 'keeping active' can be found in Figure 3. The speech bubbles used in the resources were written in the first person and capture tips and advice provided by patients during co-production of the content. These were either provided as direct quotes from individuals or ideas that were paraphrased for clarity of message and anonymity.

The user feedback survey had a target number of 50 respondents. There were 14 responses from clinicians and 62 responses from patients (n= 76) to the user feedback survey. Findings from the patients living with PsA survey supported this with 95% (n=59) identifying with the information on the website and would recommend it to friends, family or someone newly diagnosed with PsA. 98% (n=61) of patients living with PsA felt they would be ready to make change compared to before reading the materials. Similarly, 93% (n=13) of clinicians who responded agreed that it covered the information their patients were interested in and that they would be able to identify with the information on the website. 80% (n=12) clinicians

agreed that they would recommend this website to patients newly diagnosed, or with known PsA. 50% (n=7) of clinicians felt that the resources covered the right amount of depth, 30% (n=4) disagreed and 20% (n=3) neither agreed or disagreed.

The materials developed during the project are available (free of charge) for download as pdfs from the informatree website <https://www.informatree.org> and via the GRAPPA Network and Brit-PACT websites. They have also been promoted by the team and partner organisations including, the International Federation of Psoriatic disease Associations (IFPA), the Psoriasis Association and Psoriasis and Psoriatic Arthritis Alliance (PAPAA). The postcards can also be printed from high resolution PDF's to distribute to clinicians, thus aiding self-management links to clinical care.

Discussion

The advice offered in this resource was based upon the most up-to-date evidence and information available and was consistent with best practice for providing health information on behaviour change. The resources give an overview of the current non-pharmacological interventions for PsA albeit against a growing but limited evidence base. Where available, clear links to the evidence resources were provided within the web-resource. Where high quality evidence was not available, the recommendations were based on clinical expertise, and the experience of patients living with PsA.

There was a high level of patient and expert involvement in this initiative. All the key clinical (doctors, nurses and allied health professionals involved in caring for patients with PsA) and patient charity groups involved in the care of PsA in the UK were involved and patients with lived experience of PsA, and their carer's, were included at every stage.

A limitation of the project was that the limited high quality evidence base established by the literature review meant there was often no or very limited evidence to base the resources upon, and the steering group had to defer to expert opinion from within the steering group or use lower quality evidence. Although the resources created address common concerns of patients living with PsA, future research is needed to test the impact of the resource in clinical practice. The lack of available high-quality evidence to support effective methods for addressing lifestyle/behaviour change and patient self-management support to guide healthcare professionally led interventions in the clinical setting calls for additional research in this area.

The final resources created were produced in the English language. They have not been translated into other languages. They are intended to be used within the UK. Whilst the authors acknowledge that even within the UK, translation into other languages may be helpful for non-English speaking patients and communities to ensure they understand the information accurately. Unfortunately, this was not possible within the scope of this project. The resources can still be translated into other languages. However, if translated care would be need to be given with the process to ensure the medical 'jargon' and wording is translated accurately and safely to make sense for the intended patients.

A potential weakness of this project is that the website is not a living document and the information provided in the resource was accurate up to May 2021. However, the project evaluation also highlighted the need for further in-depth research on the emotional and mental health aspects of living with PsA, which means that additions to the website in the future could be possible in future reviews.

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In conclusion, this project has used a co-design approach to identify areas of unmet need, prioritised by patient and clinician groups, and to create resources to support individuals living with PsA.

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Conflicts of interest

LHH: None declared, CB has received funds for research and honoraria from the following pharmaceutical companies: Abbvie, Almirall, Amgen (was Celgene), Beiersdorf, Janssen, Novartis, Pfizer, UCB., LMH received consultancy fees from the University of Oxford for this work, SK: None declared, SM: None declared, DOS: None declared, IS: None declared, MS: None declared, LCC has been paid as a speaker for AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Medac, Novartis, Pfizer and UCB. LCC has worked as a paid consultant for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Gilead, Galapagos, Janssen, Moonlake, Novartis, Pfizer and UCB., LCC has received grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, Pfizer and UCB. LCC is a member of the RMD Editorial board.

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Ethics

Ethical approval was not sought for this project as the patient and public were involved solely in involvement activities. Their involvement informed the design of project (for example, the search strategy) and their opinions helped to co-produce the final materials. The Research Services Department at the University of Oxford were consulted and advised user feedback evaluation did not need ethical approval.

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Tables and Figures:

Figure 1. Flowchart of resource development process

Figure 2. Example of topics from informatree website

The topics are shown as they are represented on the website and the order is not intended to imply the priority of any given topic over another.

Figure 3. Example of downloadable postcard for keeping active topic

Table 1. Summary of the psychologically informed design features

COM-B component	Design features
Physical capability Psychological capability	n/a <ul style="list-style-type: none"> • Information ‘chunked’ to aid processing. • Headline message given at the top of sections. • Been selective of information included to prevent overload.
Physical opportunity	<ul style="list-style-type: none"> • Motivational interviewing is a conversation between two people. Ideally, the materials would support a behaviour change conversation in the clinic, however it was recognised that time pressure in the clinic meant this would not always be possible. Therefore, the materials were designed so that they could be used both in the clinic with professionals (handouts can be printed for use) and self-directed by patients using the website.
Social opportunity Reflective motivation	n/a <ul style="list-style-type: none"> • Non-hierarchical, patient led approach to choosing topic. In line with motivational interviewing stages (To support motivational interviewing stages of engagement and focusing). • Patient voice included via quotes (sometimes paraphrased for clarity and anonymity but based on patient comments at roundtable). Aim to normalise experience and support evidence. Fits with the behaviour change technique of social support.

Automatic motivation	<ul style="list-style-type: none"> • Asks users to identify the top three reasons making a change is important to them. Aim is to elicit internal motivation to make a change. Fits with motivational interviewing stages (eliciting) and uses behaviour change technique of self-talk. • Materials ask users to create a plan and includes questions that encourage users to think of the specifics of the plan. Fits with motivational interviewing stages (planning) and uses behaviour change techniques of goal setting and action planning. • Users asked to think ahead to what might get in the way of their plan. This is a form of the behaviour change technique action planning called implementation intentions that helps users override habitual behaviours by creating a trigger to implement their new plan. Fits with motivational interviewing stage of planning.
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Table 2. Round table groups

Group number	Purpose of group	Contributors involved	Number of people	Date of group
Roundtable 1	Concept development	Patients living with PsA	14 (run as two sessions with 6 and 8 people)	December 2020
Roundtable 2	Concept development	Patients living with PsA	10	June 2021
Roundtable 3	User evaluation	Patients living with PsA	5	July 2021
Roundtable 4	User evaluation	Clinicians	5	August 2021

Table 3. Resource topics

Topics	
1	Pain
2	Fatigue
3	Healthcare appointments
4	Tobacco
5	Different treatments
6	Alcohol
7	Work
8	Social support
9	Food and weight
10	Sleep
11	Keeping active
12	Mood
13	Intimacy
14	Travel
15	Using treatments