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Therapists' experiences of remotely delivering cognitive-behavioural or graded-exercise interventions for fatigue: a qualitative evaluation

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Abstract

Objectives: Fatigue is a challenging feature of all inflammatory rheumatic diseases. LIFT (Lessening the Impact of Fatigue in inflammatory rheumatic diseases: a randomised Trial) included remotely delivered personalised exercise programme (PEP) or cognitive-behavioural approach (CBA) interventions. The aim of this nested qualitative evaluation was to understand rheumatology health professionals (therapists') perspectives of delivering the interventions in the LIFT trial.

Methods: A subgroup of therapists who had delivered the PEP and CBA interventions took part in semistructured telephone interviews.

Results: Seventeen therapists (13 women, 4 men) who delivered PEP (n=8) or CBA (n=9) interventions participated. Five themes were identified: In 'The benefits of informative, structured training', therapists described how they were able to practice their skills, and the convenience of having the LIFT manual to refer to. When 'Getting into the swing of it', supporting patients gave therapists the confidence to tailor the content of the manual to each patient. Clinical supervision supported therapists to gain feedback and request assistance when required. In 'Delivering the intervention' therapists reported that patients valued the opportunity to address their fatigue and challenge their own beliefs. 'Challenges in delivering the LIFT intervention' therapists struggled to work collaboratively with patients who lacked motivation or stopped engaging. Finally, 'Lift developing clinical skills' therapists gained confidence and professional satisfaction seeing patients' fatigue improve.

Conclusion: Findings support the value of skills training for rheumatology health professionals to deliver a remote fatigue management intervention tested in the LIFT trial. These insights can inform service provision and clinical practice

Key words: fatigue; qualitative; exercise; cognitive-behavioural approaches; rheumatic diseases.

Key messages:

- Skills training for rheumatology health professionals can be used to successfully deliver fatigue management interventions remotely.
- Therapists described increased professional satisfaction and confidence seeing patients' fatigue improve.
- These insights inform strategies for service provision and clinical practice for remotely-delivered support.

Lay summary

What does this mean for patients?

Fatigue can be a challenge in inflammatory rheumatic diseases (IRDs). The LIFT study (Lessening the Impact of Fatigue in inflammatory rheumatic diseases: a randomized Trial) explored interventions to support people with fatigue. These were: a cognitive-behavioural approach (CBA), a personalized exercise programme (PEP), or usual care. People with IRDs were chosen randomly to take part in seven sessions of CBA, seven sessions of PEP or usual care. All sessions (aside from the first PEP session) were delivered over the phone. The aim of this study was to explore therapists' experiences of delivering the intervention. Seventeen therapists (13 women and 4 men) took part; eight had delivered the PEP intervention, and 9 delivered the CBA intervention. Therapists who delivered LIFT told us they enjoyed the chance to practice their skills, and that the LIFT manual gave them the confidence to tailor the intervention to each patient. Clinical supervision was valued. Therapists also shared that LIFT improved their skills and they were happy to see patients' fatigue improve over time. These new results can inform clinical practice, and how services are provided.

Introduction

Fatigue can be an overwhelming and distressing feature of inflammatory rheumatic diseases (IRD). Most of the evidence to date has come from studies in rheumatoid arthritis (RA), which have established that between 42% - 80% of patients experience significant fatigue which they can find difficult to manage(1-3). Similar findings have been reported for other IRDs, including systemic lupus erythematosus (4) and ankylosing spondylitis (5-7).

A qualitative metasynthesis found that patients often experience fatigue as an unpredictable and pervasive symptom with physical, cognitive, emotional and social effects(8). The authors concluded that it is important for health professionals to acknowledge the impact of fatigue on the patients' everyday lives and provide support to develop strategies to cope well, increase physical activity and maintain work(8). This is consistent with a systematic review of non-pharmacological interventions which found evidence to support psychosocial and physical activity interventions(9).

Although cognitive-behavioural based approaches have been widely used within psychology, a growing need for non-psychologically trained healthcare professionals to deliver psychologically-informed care has been recognised (10-12). There are a number of examples within the literature of healthcare professionals being trained in new, psychologically informed skills, such as cognitive behavioural approach (CBA) training, including CBA interventions for low back pain, delivered by trained nurses in primary care (13). Similarly, the RAFT trial (Reducing Arthritis Fatigue- clinical Teams), a seven-session group course for people with RA-related fatigue, was delivered by trained rheumatology healthcare professionals (occupational therapists and nurses) using cognitive-behavioural principles (14). As access to clinical psychology within rheumatology teams is not always

available, and may be difficult for patients to access (14), if healthcare professionals could be trained to deliver an effective CBA intervention, this could potentially offer benefit to patients with IRD-related fatigue.

Lessening the Impact of Eatigue in inflammatory rheumatic diseases: a randomised Trial (LIFT) is a multi-centre three-arm randomised trial using a remotely delivered personalised exercise programme (PEP) or cognitivebehavioural approach (CBA) intervention, in addition to usual care (a Versus Arthritis patient information leaflet)(15). Further detail about the LIFT intervention has been published separately(16). The interventions were designed to facilitate cognitive and behaviour change, enhance patients' coping and self-management and reduce the severity and impact of their fatigue. The intervention was delivered by health professionals (termed therapists in this article) who were members of NHS staff at each research site; CBA by a rheumatology nurse or equivalent allied health professional, such as an occupational therapist, and PEP by a specialist physiotherapist, usually with a rheumatology background. Participants with IRD in the intervention arms were randomised to seven one-to-one sessions of either the PEP or CBA interventions delivered by trained therapists over 14 weeks, plus a booster session at 22 weeks. Sessions were delivered via telephone, or by videoconference, depending on patient preference. In the PEP arm only, the first session was delivered face-to-face(15). For the PEP intervention, participants completed detailed physical activity diaries, and set personalised goals relating to what they wanted to achieve from the programme (16). This data was used to plan a personalised progressive exercise programme, in agreement between the therapist and participant(16). In the CBA intervention, participants were given basic information about how cognitive, behavioural, emotional and biological factors can interact to impact fatigue. Participants were encouraged to develop a problem statement that described their own fatigue in terms of these factors, and were encouraged to set goals, complete activity diaries, completed homework activities and participated in review and feedback about the intervention(16). Progress was reviewed in each session, and new goals put in place if required (16).

Therapists delivered the LIFT intervention after separate PEP and CBA training sessions. Initial training for PEP was two days, with additional training for new therapists reduced to 4-5 hours on a single day. Initial training for CBA was three days with additional training for new therapists reduced to two days. In both PEP and CBA training, more efficient and shorter training was used for subsequent sessions. Training was delivered face to face by experienced clinical academics (AW, KL, LP) and featured vignettes of fatigue cases, role play and skills practice(15). During the period that they were delivering the interventions to trial participants, therapists had access to clinical supervision every two weeks or as needed. Clinical supervision was provided by AW, KL, SG or LP via telephone(15). The aim of this study was to evaluate therapists' experiences of intervention training and delivery as part of the LIFT trial.

Methods

We used qualitative methods and collected data in semi-structured telephone interviews with a subgroup of LIFT therapists who had delivered the PEP and CBA interventions in the LIFT RCT. Qualitative methods are well suited to in-depth exploration of topics(17, 18). The interview schedules for the PEP and CBA arms are outlined

in Supplementary Data S1, available at *Rheumatology Advances in Practice* online, and featured open-ended questions deigned by the study team. Questions explored therapists' reasons for taking part in LIFT, prior relevant experience, thoughts on the training and delivery, impact on the therapists' clinical practice, and any suggestions for changing the intervention for future roll out.

Sample

 All therapists who had delivered LIFT intervention sessions at the six participating NHS sites were eligible to take part. LIFT therapists were sent invitations to take part in the nested qualitative evaluation sub study (n=27) after they had completed their delivery as part of the trial. Therapists returned reply slips to the first author (SB) to express an interest in taking part. All therapists provided written informed consent for the qualitative component. To maintain anonymity, participant codes have been used throughout.

Data collection

Interviews were conducted by CA and SB, research associates with prior experience of conducting telephone interviews but with no involvement in the design or delivery of the LIFT training or interventions. Before the start of each interview, therapists were reminded that the call was being recorded, the procedure for anonymisation and what the aims of the interview were, and they were given the opportunity to ask any questions.

Data analysis

Audio recordings were transcribed by an approved transcription service, anonymised, and checked for accuracy against the original audio recordings. The transcripts were imported into in NVivo 12 (released in 2018)(19) and analysed using inductive thematic analysis as outlined by Braun and Clarke, a data-driven approach with no overarching framework applied to the data 'a priori'(20). The underpinning perspective was realist with analysis at the latent level. The first author SB read through all the transcripts and coded text that related to the research questions. Codes were reviewed, revised and organised into overarching themes and subthemes, with some codes raised and upgraded into themes, while less relevant codes were discarded(20). Data saturation was determined when no new themes were identified from therapist interviews(21). Two transcripts were independently reviewed by four co-authors (ED, CA, AW and KL) and the themes and subthemes discussed as a team to reach consensus. Themes and subthemes identified in the thematic analysis can be seen in Table 1.

Ethics

The study complied with the Declaration of Helsinki, and was approved by the Wales Research Ethics Committee Number 7 (reference: 17/WA/0065). Informed consent was obtained from all participants.

Results

 A total of 17 therapists (13 women, 4 men) from the PEP (n=8) and CBA (n=9) arms responded and were able to participate in telephone interviews. Interviews were conducted between July 2019 and August 2020. Therapists who did not respond to invitations to participate were not interviewed, therefore any reasons for non-participation in the interviews were not recorded. The 17 therapists who were interviewed had attended one of four training sessions; 3-day in-person training (n=6), 2-day in-person training (n=5), 4-hour intensive inperson training (n=3), or 4-hour intensive remotely-delivered training (n=3)." This reflects the health professionals joining the LIFT study at different time points. Interviews lasted between 25 and 45 minutes (average 34 minutes).

Table 1 here please.

The benefits of informative, structured training

Therapists valued the ability to train with other rheumatology health professionals before delivering the intervention. Many identified the benefits of having informative and structured training to guide them in delivery.

Mixing it up (benefits of training)

Although role play was not everyone's "favourite thing" [T02 CBA], a variety of methods helped therapists to practice their skills before meeting patients. Therapists approved of the variety in the content and delivery of their training, as it enabled them to stay focused.

"We weren't sitting – they were mixing it up, they were taking turns talking, we were doing exercises and being included, so they ... kept our attention right throughout the day and good breaks and things. It was ideal. I wouldn't change a thing." [T07 CBA]

"With the exercise cohort, there was a face to face appointment, so we did a bit of role-playing for that and a bit of role-playing for the telephone as well." [T14 PEP]

A lot to take in at once

This subtheme captures the challenges that therapists encountered during the training for their role.

Training times varied, from two days to four hours. There was a lot to absorb and learn in the longer training sessions "It was...quite a lot of information to take in at one go." [T12 PEP]. However, those in the shorter training sessions, felt that they would have liked more time to practice their skills before meeting with patients.

"[In 3-day training] people had opportunities to do a bit of role playing whereas we kind of tended to gloss over that a bit because we only had two days ... if we'd done a bit more role playing, it would have been helpful." [T05 CBA]

Nervous, but keen to try

 Most therapists felt nervous before delivering the intervention and meeting LIFT participants for the first time, but found that they grew more confident with practice; "I did feel a bit anxious about that in the beginning, but actually the more I practiced at it, the easier it became." [T09 CBA]. After training, this therapist described; "I felt quite confident that I knew what I was doing. Certainly, once I went through my first patient from start to finish ... it was confidence as you go" [T12 PEP].

Getting into the swing of it

Once therapists had embarked upon the LIFT trial, they described how the chance to apply and make use of their training improved their confidence. The therapists spoke of liking the manual as a resource to refer to, alongside support from professional supervision.

Therapist utilisation of the training manual Although almost all therapists described being nervous at the start of delivering the interventions to participants, the chance to practice and the support provided by the manual gave them the confidence and flexibility to tailor content to individual patients' needs, and to jump back and forth between sections of the intervention.

"Sometimes I use them more or less in order sometimes I jump back and forth. No, I've kind of got into the swing of it now." [T03 CBA]

"The better you become the slicker you become" [T08 CBA]

Therapists gave very positive feedback regarding the intervention manual, which many liked to keep close by during sessions, "I could look at that while I was on the phone ... I actually could look at it quite confidently." [T17 PEP].

Some therapists suggested a digital copy, both to prevent the paper bound manual from becoming worn with regular use, and to make navigating to key content easier.

"I did find it difficult to use during sessions because it's big and hard to find things, but they're all where they should be and it's well-designed...it's just the nature of that much information and being able to locate it ... If I had it open as a PDF I could do a quick search" [T10 PEP].

Supervision gives 'input from a different angle'

 The clinical supervision provided to therapists by the LIFT trainers, allowed them to query their own practice, get feedback on their performance, and ask for input and assistance on more difficult interactions.

"Trying to figure out how to apply it is a difficult thing, and that's where the supervision was really handy because it just comes at a different angle than I'm used to." [T03 CBA]

"That gave me confidence as well ... I knew that somebody was on the end of the phone that could actually answer your question." [T15 PEP]

Delivering the intervention

Therapists had the option to deliver the intervention using telephone or internet-based audio-video calls, according to patient preference. However, only the telephone option was taken up. Although many therapists had not used remote delivery prior to the intervention, they found telephone delivery to be straightforward.

Building rapport

The first face-to-face session that was part of the PEP delivery enabled therapists to build rapport with participants; "Because all of the participants I met one to one for their initial appointment so I could visualise them and I knew what their capacity and things were" [T15 PEP]. Similarly, although the face-to-face session was not an element of the CBA arm, therapists still enjoyed the opportunity to build a good relationship with participants; "Each time you feel like you get to know them a bit more and you recognise their voice ... I remember you, it's nice to speak to you again" [T04 CBA].

More open communication

Therapists reported that participants were able to talk about their fatigue and seemed more open in telephone communication; "[LIFT] worked better because it was over the phone, because there was a level of control that people had, so far as they weren't presenting all of themselves...It was good for them to have ...a barrier that they could report and still feel independent." [T10 PEP] Participants could challenge their own beliefs about fatigue and the causes of their fatigue; "[LIFT] gave them a different view on their condition and maybe how they can look at things... they looked at things differently and they said they had tools to carry on and manage their fatigue." [T02 CBA], with LIFT giving them the tools to better manage their fatigue themselves.

Challenges in delivering the LIFT intervention

Patients unable or unwilling

LIFT therapists struggled to engage participants who were unable or unwilling to change their selfmanagement behaviours, in both the PEP and CBA arms: "They tell [you] they try, but they don't really, you can tell that it's not really going to change. One of them said to me, "I know what I have to do, I'm just not really in the right frame of mind to change some habits." [T01 CBA]

"You wouldn't necessarily feel like they'd actively changed their everyday life, which for some of them, they needed to." [T16 PEP]

Patients underestimating the work required

 Therapists reported that a minority of participants had not realised "how much …work on their side they've got to do" [T08 CBA] for them to get the best results from the LIFT interventions and see the greatest benefit. Therapists described these difficulties:

"The thing that put most people off initially was the first diary and the amount of homework and being organised, and how to share that information back" [T12 PEP]

"By session three you could see who were the patients that were going to try and apply all this advice and the ones that were just really not interested ... Expecting like a magic wand to come out and sort out their fatigue...

They were not quite prepared to put in the work themselves." [T01 CBA]

LIFT helping own practice going forward

Professional satisfaction

Therapists expressed enthusiasm and professional satisfaction in seeing participants' fatigue improve and the positive changes made in their lives because of their involvement in the LIFT RCT.

"I got a huge amount out of it, and the patients were great I have to say and I really... it was a great... when they were getting further and making progress and seeing differences themselves it was a real boost I think, for them and for me ... that we were able to manage all this by phone and that they could see a difference in their lives." [T05 CBA]

"I felt like had totally changed her life, and sort of socially, personally, professionally, just everything, she was like a different person. And that was really lovely, and I felt like I got to the end of it and thought, "I've really made a difference" and I can see how the results of this would really show huge benefits." [T16 PEP]

Implementing the LIFT intervention in daily practice The skills and tools acquired by therapists during LIFT training gave them greater confidence in the advice and support they offered to patients.

"I don't think I wasn't saying the right thing before, I just was not as confident ...we just referred them to the occupational therapist, whereas now I can just do the advice myself, and if I do have the time I do explain how behaviours and thoughts can affect the way we act and how it's all connected." [T01 CBA]

"I'm not scared to get them doing more ... [When] fatigue's a big issue you think, "Oh, I don't want them overdoing things", whereas now I know that it helps... I'm not as reluctant... it's certainly improved the overall management." [T12 PEP]

"[LIFT] feels like the missing link to we what we were always doing. It's made a massive difference, we were getting quite good results with the fatigue group, but I kind of felt like there was something missing and I feel this has absolutely been it...listening, not trying to think of solutions and getting patients to come up with that themselves and that's what's made the difference, without a doubt." [T07 CBA]

An intervention that still works with COVID

Many therapists shared ideas about how the interventions could be rolled out clinically. The only limitations to the intervention working remotely, was securing private clinic space to make phone or video calls to participants. To facilitate communication with patients, therapists suggested the option for video consultations, call headsets, and using a data sharing app:

"Certainly now after Covid, there's a lot more telephone work going on. ... theoretically, I guess, I could have done [LIFT] from home." [T09 CBA]

"A face to face type video chat might have been a bit more engaging. It was all phone calls, and you needed that first face to face, I think, session to get buy-in and build that rapport with your patient to get them to engage with the format, so probably something a bit more similar" [T12 PEP]

"I do think video link is the way to go if patients are able to do that. Because it's nice to see somebody and also the only drawback of the phone was I would have liked to have seen patients' activity diaries." [T05 CBA].

Discussion

While rheumatology teams are increasingly aware that fatigue can be a challenging symptom for patients to manage, they have very few treatment options available to help (22). These results have highlighted the benefits of health professionals receiving structured training and learning skills to support patients with fatigue. Although seen as awkward by some therapists, the use of role play during training allowed them the chance to practice their skills before undertaking sessions with patients. Role play encourages participation and the adoption of an identity, based on simulated scenarios, for educational purposes(23). In modern medical education, role play is typically used to develop communication and critical thinking skills in clinical practice(24) and to enable health professionals to experience the imagined perspectives of the clinician and the patient(23). In the present study, some patients showed a lack of engagement with the intervention. Although financial and time constraints on therapists time could potentially limit what can be offered to patients, there is potential for future therapist training to focus on engaging participants who were less willing to take part in in the intervention. The benefits of skills training for rheumatology nurses, occupational

therapists and physiotherapists to support patients with fatigue have been highlighted in self-management interventions for multiple sclerosis (MS)(25) and RA(26). Healthcare professionals who undertook an intensive self-management programme for patients with RA, described how techniques such as motivational interviewing had seemed difficult initially, but had become easier with practice and had increased their professional confidence in supporting patients(27).

A further benefit of the LIFT RCT was the clinical supervision that therapists could access. Supervision has been cited as a helpful element of other interventions, including delivery of a group fatigue intervention for RA patients by clinical teams(26). Although the supervision in this study was provided by experienced professionals to their less experienced colleagues, peer support may offer a more realistic and achievable model within NHS care that is worth pursuing in further studies. This may be particularly relevant in busy rheumatology departments(28), for example, a rapid review of clinical supervision in the NHS found that peer supervision was perceived as a positive form of support. Helpful elements included supervisors' self-disclosure regarding their own experiences, helping to normalise the supervisees' experiences and encouraging them to share their viewpoints (28, 29). For these benefits to influence patient care, it is vital that supervision be given regularly, with protected time for staff to take part in supervised practice (28).

Few LIFT therapists had previous experiences of delivering care over the telephone, but they were able to work effectively with remote delivery. Although some concerns have been raised regarding the potential disadvantages of telephone delivery, such as the inability to see facial expressions (30), and some patients have voiced scepticism(31), a recent systematic review comparing remotely delivered and face-to-face CBT interventions found no significant effect on patient-therapist interactions (32). Remotely-delivered exercise interventions using videoconferencing were found to result in significantly greater 12-week weight loss, compared to in-person or usual care arms,(33) or a control group (34). Telephone delivery offered several advantages to both participants and therapists. Although this study was designed and delivered prior to the COVID-19 pandemic, therapists commented that most patient-facing rheumatology services had changed to remotely delivered consultations since March 2020.

While the PEP and CBA interventions were perceived positively by therapists, they had several ideas for improvements before rolling them out to more NHS sites. These included the more widespread use of video consultations to facilitate communication, particularly when explaining exercises in the PEP intervention or sharing pictorial information, such as activity diaries in the CBA intervention. Ideas for making data sharing between therapists and patients more streamlined were proposed, such as using a secure data-sharing app. In addition, future research could also explore the more cost-effective and practical means of delivering the intervention across a wider range of NHS sites, and at lower cost. Future economic evaluation and analysis would be beneficial, to evaluate whether the LIFT intervention offers cost savings compared to usual care.

Strengths and limitations

A strength of this research is that therapists were contacted after they had finished delivering the interventions, giving them the opportunity to reflect on the whole process. Therapists in this study were based at six hospital sites across the UK and seemed very open to communicating about their experiences. This enabled exploration of a variety of viewpoints from therapists working in a range of clinical settings, serving different communities and with different local infrastructures that might impact their experiences. A limitation is the small sample size of participants (n=17) recruited to the qualitative evaluation sub study. In addition, interviews with therapists after training, and prior to delivery of LIFT, may have given more detail about their thoughts prior to starting the intervention.

Conclusions

These findings support the value of skills training for rheumatology health professionals to deliver PEP and CBA fatigue management interventions remotely. Therapists described many positives of the LIFT interventions, including professional satisfaction at seeing patients' fatigue improve, increased confidence in supporting patients with fatigue, and the challenges and benefits of learning new skills. Valuable therapist-proposed ideas for positive changes to the LIFT interventions, to improve efficiency of delivery and information sharing have been proposed, which can be considered for wider roll out of the interventions in the future. Further research could also consider the most cost effective and practical way to deliver the intervention across a wider range of study sites. These insights can inform service provision and clinical practice for remotely delivered support of rheumatology patients with fatigue.

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Data availability statement: The data underlying this article cannot be shared publicly due to ethical reasons, to protect the privacy of individuals that participated in the study.

Table 1: Themes and subthemes identified in the thematic analysis.

| Theme | Subthemes |
|---|---|
| 1. The benefits of informative, structured | Mixing it up (benefits of training) |
| training | 3 , (3 3) |
| | A lot to take in at once |
| | Nervous, but keen to try |
| 2. Getting into the swing of it | Therapist utilisation of the training manual |
| | Supervision gives 'input from a different angle' |
| 3: Delivering the intervention | Building rapport |
| | More open communication |
| 4. Challenges in delivering the LIFT intervention | Patients unable or unwilling to engage |
| | Patients underestimating the work required |
| 5. LIFT developing clinical skills | Professional satisfaction |
| | Implementing the LIFT intervention in daily practice An intervention that still works with COVID |

LIFT: Lessening the Impact of Fatigue in inflammatory rheumatic diseases: a randomised Trial.

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A 2nd generation, JAK1 preferential inhibitor for moderate to severe RA1-6

While 1st generation JAK inhibitors are relatively non-selective,2-6 JYSELECA has over 5x greater potency for JAK1 over JAK2/3 and TYK21*

Balancing sustained efficacy⁷⁻¹¹ with acceptable tolerability^{1,12}



Indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs.¹ May be used as monotherapy or in combination with methotrexate.1

*From biochemical assays, the clinical relevance of which is uncertain. JAK, Janus kinase; RA, rheumatoid arthritis; TYK, tyrosine kinase.

Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

JYSELECA® Tilgotinib 100 mg or 200 mg film-coated tablets. Indication: Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDS). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). Dosage: Adults; 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. Laboratory Monitoring. Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. Elderly: A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. Renal impairment: No dose adjustment required in patients with estimated creatinine clearance (CrCl) ≥ 60 mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to 60 mL/min). Not recommended in patients with crCl < 15 mL/min. Hepatic impairment: Mild/moderate hepatic impairment: not recommended. Children (< 18years): Safety and efficacy not yet established. Contraindications: Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. Pregnancy. Warnings/Precautions: See SmPC for full information. Immunosuppression: combination use, with immunosuppressants e.g., ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression combination use, with immunosuppressions infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB) oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be assessed prior to initiating in patients with risk factors for infections (see SmPC). Patients should be closely monitored for t

is not responding to antimicrobial therapy, until infection is is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. <u>Tuberculosis</u>: Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. <u>Viral reactivation</u>: Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. Malignanoy: Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). Fertility: Inanimal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. Haematological abnormalities: Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) <1 × 10° cells/L, ALC <0.5 × 10° cells/L or haemoglobin <8 g/dL. Temporarily stop therapy if these values are observed during routine patient management. Vaccinations: Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. Lipids: Treatment with filgotinib was associated with dose dependent increases in lipid is not recommended. <u>Lipids</u>: Ireatment with fligotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). <u>Cardiovascular risk</u>: Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors cardiovascular disorders. Fateients should nave risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. <u>Venous thromboembolism</u>: Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors

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immobilisation. Lactose content: Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take filgotinib. Pregnancy/Lactation: Filgotinib scontraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment. Driving/Using machinery: No or negligible influence, however dizziness has been reported. Side effects: See SmPC for full information. Common (21/100 to 1/100); herpes zoster, pneumonia, neutropenia, hypercholesterolaemia and blood creatine phosphokinase increase. Serious side effects: See SmPC for full information Legal category: POM Pack: 30 film-coated tablets/bottle Price: UK Basic NHS cost: E863:10 Marketing authorisation number(s): Great Britain Jyseleca 100mg film-coated tablets PLGB 42147/0002 Northern Ireland Jyseleca 100mg film-coated tablets EUJ/120/1480/001 200mg film-coated tablets PLID8 42/14/100U2 Northern Ireland lyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004 Further information: Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UBB 1QS, United Kingdom 00800 7878 1345 medicalinfo@glpg. com Jyseleca® is a trademark. Date of Preparation: January 022 UK-RA-FIL-202201-00019

Additional monitoring required

Adverse events should be reported.
For Great Britain and Northern Ireland, reporting forms and information can be found at <u>yellowcard.mhra.go</u> or via the Yellow Card app (download from the Apple Store or Google Play Store).

Adverse events should also be reported to Galapagos via email to DrugSafety.UK.Ireland@glpg.com

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