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Title: Feasibility of Daily Pain Measurement Using Text Messages in Hidradenitis Suppurativa Clinical Trials; Data from THESEUS Study

SB Hasan¹, J Bates², R Cannings-John², F Collier³, J Evans², A Gibbons⁴, C Harris⁴, L Howells⁵, K Hood², R Howes⁶, P Leighton⁵, M Riaz², J Rodrigues^{7,8}, H Stanton², K S Thomas⁵, E Thomas-Jones⁵, JR Ingram¹

Samar B Hasan¹, ORCID = 0000-0002-3265-4530
Janine Bates², ORCID = 0000-0003-3610-2415
Rebecca Cannings-John², ORCID= 0000-0001-5235-6517
Fiona Collier³ ORCID = 0000-0001-5271-9170
Judith Evans²
Angela Gibbons⁴, ORCID = 0000-0001-5285-4954
Ceri Harris⁴, ORCID = 0000-0002-0462-7789
Laura Howells⁵, ORCID = 0000-0003-4157-7394
Kerenza Hood², ORCID = 0000-0002-5268-8631
Rachel Howes⁶, ORCID = 0000-0002-6120-8433
Paul Leighton⁵, ORCID = 0000-0001-5208-0274
Muhammad Riaz², ORCID = 0000-0002-5512-1745
Jeremy Rodrigues^{7,8}, ORCID = 0000-0002-9347-5026
Helen Stanton², ORCID= 0000-0003-0197-3667
Kim S Thomas⁵, ORCID = 0000-0001-7785-7465
Emma Thomas-Jones², ORCID = 0000-0001-7716-2786
John R Ingram¹, ORCID = 0000-0002-5257-1142

Affiliations

1. Division of Infection & Immunity, Cardiff University.
2. Centre for Trials Research, College of Biomedical & Life Sciences, Cardiff University.
3. NHS Forth Valley, Scotland
4. Public Contributors
5. Centre of Evidence Based Dermatology, School of Medicine, University of Nottingham
6. Dept of Plastic Surgery, John Radcliffe Hospital, Oxford NHS Trust
7. Dept of Plastic Surgery, Stoke Mandeville Hospital, Buckinghamshire Healthcare Trust
8. Warwick Clinical Trials Unit, University of Warwick

Corresponding author

Dr Samar Hasan, hasansb1@cardiff.ac.uk

Declarations of Conflicts of Interest:

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Data Availability

All data requests should be submitted for consideration to: ctrdatasamplerequests@cardiff.ac.uk. Access to anonymised data may be granted following review.

Ethics statement

The Wales Research Ethics Committee 4 provided ethical approval for THESEUS on 26 September 2019, reference number 19/WA/0263.

Dear Editor,

Pain can be a highly disabling symptom frequently experienced by individuals with hidradenitis suppurativa (HS), ranking as the most impactful item in the HS core domain outcome set.(1) A scoping review of how pain is measured in randomised controlled trials (RCTs) for painful skin conditions and rheumatoid arthritis found that the 0-10 Numeric Rating Scale (NRS) and Visual Analogue Scale (VAS) are the most commonly used instruments.(2) However, there was heterogeneity in how these instruments were used in the included RCTs, in terms of frequency of measurement, recall window, and average versus maximum pain.

Treatment of Hidradenitis Suppurativa Evaluation Study (THESEUS) was an observational study involving 10 centres in the UK.(3) The main aims of THESEUS were to improve the understanding of current treatments for HS, to prioritize therapies for future RCTs, and to contribute to validation of outcome instruments.(1)

The THESEUS study explored the feasibility of daily pain NRS measurement collected via text messages for 12 weeks after an intervention commenced. The message asked *"Please indicate the level of pain you are CURRENTLY experiencing due to your HS. The scale is from 0 - 10. '0' means no pain and '10' means pain as severe as it could be."* It was sent each day at 6pm and participants had until 2am the following day to respond. Participants responded with a number from 0 to 10 with a free of charge text message. Patient's could send an 'Opt Out' response to discontinue the text messages. In addition, participants were required to complete several questionnaires every three months during the follow up period.

146 out of 150 participants consented to receive daily text messages, of whom 110 (75%) participants received at least one text message due to logistical issues. Firstly, the system did not automatically send the messages when the intervention was initiated at the beginning of the trial (n=20) and secondly some participants did not commence their

intervention (n=16). Of the 110 participants who received a text message, 10 did not return any messages. 100 participants returned at least one message and 4,898 texts were received in total. Of the participants who returned at least one text message, 86% were female, 80% were White and 20% were Black, Asian, Caribbean or mixed ancestry, with ages ranging from 19 to 67 years. Eighteen (18%) participants requested that the text messages be discontinued.

Figure 1 details the number of participants who provided a text message response each day. Response rates were 70%, 60%, 55%, and 20% after two, four, eight, and 12 weeks respectively. Participants who had more severe disease were more likely to provide a pain score.

Interviews with study participants identified a number of themes.(4) Several participants had a positive experience and found the daily text messages to be helpful in monitoring their HS. These participants found the process simple and easy and got into the habit of responding to the daily messages.

Some patients reported issues with the text messages. Several were not made aware of the duration of the text messages and so were concerned when the texts stopped. Additionally, delay in receiving the texts when there was a delay in the initiation of THESEUS laser or surgical interventions caused confusion to some participants. Some thought it was unproductive to continue responding when their HS was in remission and their responses documenting no or low pain scores became repetitive. Others stopped responding because they had other non-HS related problems or preferred not to receive the daily reminder to submit their pain score.

Regarding limitations of our study, it only assessed one method of collecting pain data. Text messages were chosen to avoid data storage confidentiality issues and to keep access to the collection method as wide as possible. A few participants may not have a mobile phone and a paper diary could have been a substitute method. Future studies should consider providing specific documentation detailing the duration of the text messages and instructions to continue responding even when there has been no change in pain to improve the response rate.

The results suggest that daily pain scoring may be a feasible option for a brief durationsuch as for two-week periods when the response rate was 70%. Short term daily collection could be centred around a scheduled trial visit. We recommend avoiding long term daily collection of pain scores, with response rates falling to 20% after 12 weeks. The frequency of pain score collection remains a balance between minimising responder burden while not missing interval changes, (5)

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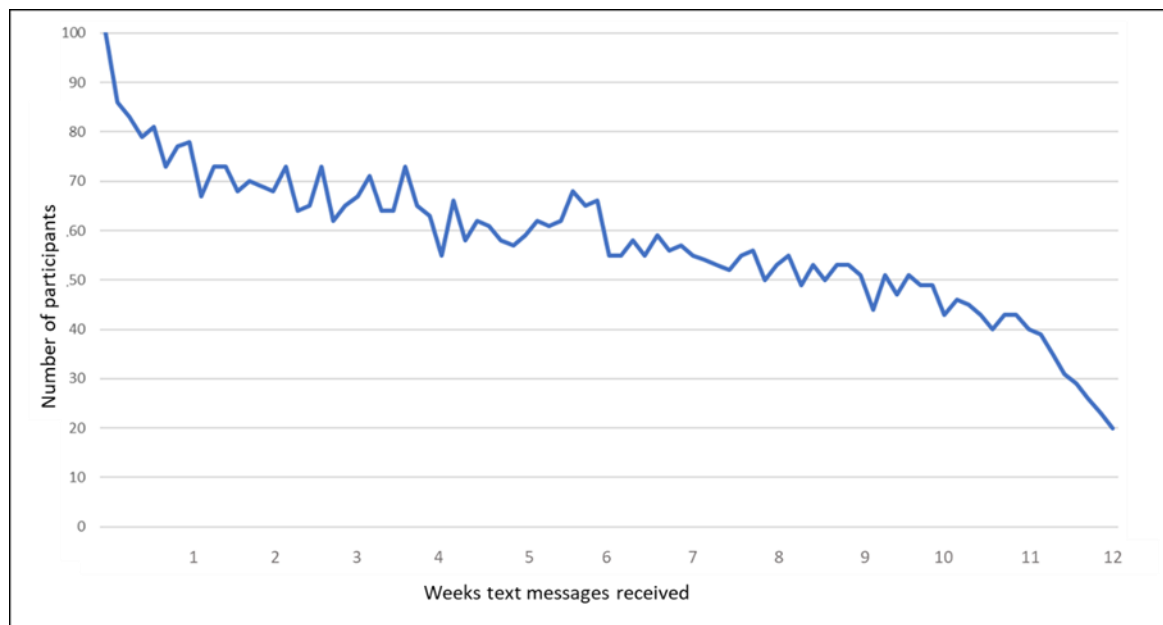


Figure (1). Line graph of the daily response rates of participants over twelve weeks (84 days)