



TRIAL PROGRESS

Clinician Survey

Over the last six months, the BETTER-B team have been hard at work to continue recruitment and finalise the clinician survey on breathlessness (Work Package 1).

Recruitment

Our sites in the UK, Ireland, Australia and Germany have been successfully screening and recruiting eligible participants, with some now already finished their time in the BETTER-B trial. Recently, recruitment efforts were unfortunately affected by the fourth wave of the COVID-19 pandemic. We are working to mitigate the effects that COVID has on our programme and are aiming to keep our recruitment rate high.

Our two Italian sites in Reggio Emilia (Santa Maria Nuova and Correggio) have recently also opened to recruitment. Our research team there have spent the last few months thoroughly preparing for their site opening and have hit the ground running after opening.

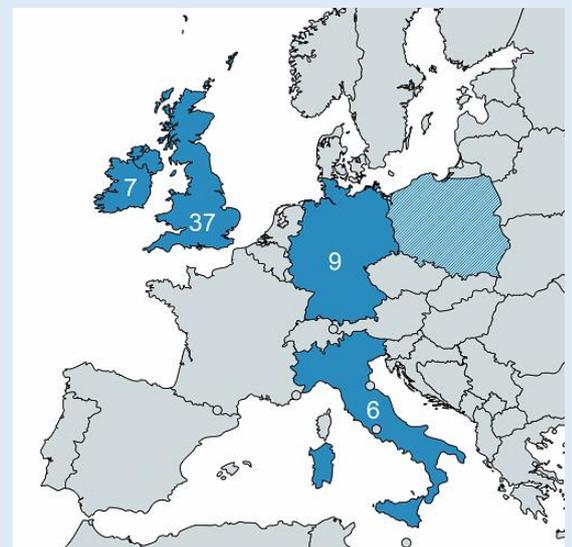
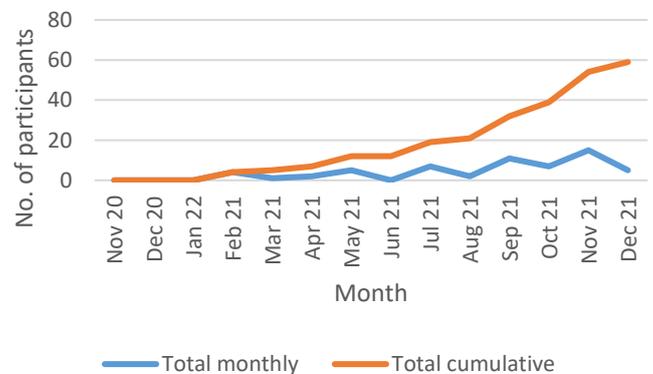
We are very close to opening the last two sites in Poland and Italy (Rome) and are hopeful that we will finish the approval process in January 2022.

RECRUITMENT NUMBERS OVERVIEW

Here you can find an overview of our current recruitment numbers. With the trial period being planned to run until July 2022, you can see that we still have some work to do. The main reasons for the low recruitment figures in some countries are due to delayed site openings as a result of the COVID-19 pandemic. We are trying our best and remain hopeful that we can meet our expected recruitment targets by the summer of 2022.

Recruitment site	Date opened	Total no. of randomised participants	Recruitment target
Castle Hill Hospital Hull/York	Nov 17th 2020	9	15
King's College Hospital	Dec 1st 2020	22	60
Nottingham City Hospital	Dec 8th 2020	6	25
St. Vincent's University Hospital	May 7th 2021	7	30
University Hospital of Munich	July 13th 2021	5	30
University Hospital of Köln	July 22nd 2021	3	15
Solingen Centre for Sleep and Respiratory Medicine	Sep 20th 2021	1	15
Santa Maria Nuova, Provincial Hospital	Nov 11th 2021	3	20
Hospital San Sebastiano di Corregio	Nov 24th 2021	3	40
IRCCS "A. Gemelli" University	Due to open Jan 22		30
Gdansk University Clinical Centre	Due to open Jan 22		50
Total randomised		59	330

Monthly & cumulative recruitment (Nov 20-Dec 21)



PROTOCOL AMENDMENTS TO ENABLE REMOTE PARTICIPATION

To compensate for the recruitment difficulties brought about by the re-emerging COVID-19 pandemic, we made two important changes to our study protocol.

Our first amendment allows us to perform the consent process remotely, using videocall or telephone. This enables us to recruit participants without them having to visit the clinic.

Additionally, to ensure the safety of our participants and researchers, we amended the protocol to allow us to send trial medication via a courier service and also carry out remote monitoring visits.

BETTER-B AT THE EAPC CONGRESS 2021

The bi-annual EAPC World Congress took place online from the 5th-8th October. The BETTER-B consortium was well represented, with many of our researchers presenting their work or chairing sessions. Additionally, one Parallel Session was devoted to the topic of opioid treatment options for chronic breathlessness.

BREATHLEASE STUDY COMPLETED

We would also like to draw your attention to the recent completion of the BreathEase study at LMU University Hospital Munich, which also focused on the treatment and alleviation of breathlessness. The BreathEase study team has compiled a handbook for non-pharmacological treatments for breathlessness which has been sent out to participants.

3 QUESTIONS FOR... STEFFEN SIMON, UNIVERSITY HOSPITAL KÖLN

1. What is your role in the BETTER-B project?

I am the Principal Investigator for the Center of Palliative Medicine at the University Hospital in Cologne. We are a recruiting site in the Better-B trial. In addition, I am the lead of WP6 aiming to develop an ERS short guideline about the effect of anti-depressants for the relief of chronic breathlessness which includes a systematic literature review and a consensus process. Furthermore, I take part in other WPs in a minor role.



2. What is your academic background?

I am a physician (internal medicine, palliative medicine) and consultant for palliative medicine at the University Hospital of Cologne. I am the lead of the multi-professional hospital palliative care team at our hospital caring for nearly 1000 patients with life limiting disease every year including patients on ICUs. My research group focus on conducting studies in the area of breathlessness (incl. episodic breathlessness) and in the area of haematological malignancies, e.g. patients with allogenic stem cell transplantation. I received my MSc in Palliative Care from the Cicely Saunders Institute (CSI) at KCL in London, and worked for three years at the CSI. There, I learned a lot about how to conduct and set up studies and about research methods in general.

3. Why did you join the BETTER-B research consortium?

Drug trials in palliative care are rare especially in the area of breathlessness. There is a strong need for more pharmacological options to treat breathlessness as we only have morphine/opioids. I am taking part in order to enhance the evidence for a better relief of breathlessness. In addition, it is fun to work hard together with lovely and congenial people.

For more information please contact better-b@kcl.ac.uk or visit our website betterbreathe.eu.

BETTER-B is funded by the European Union's Horizon2020 research and innovation programme under grant agreement No. 825319