# NEWSLETTER JULY 2021

# Over 4,400 WOMEN RANDOMISED

# WELL DONE!

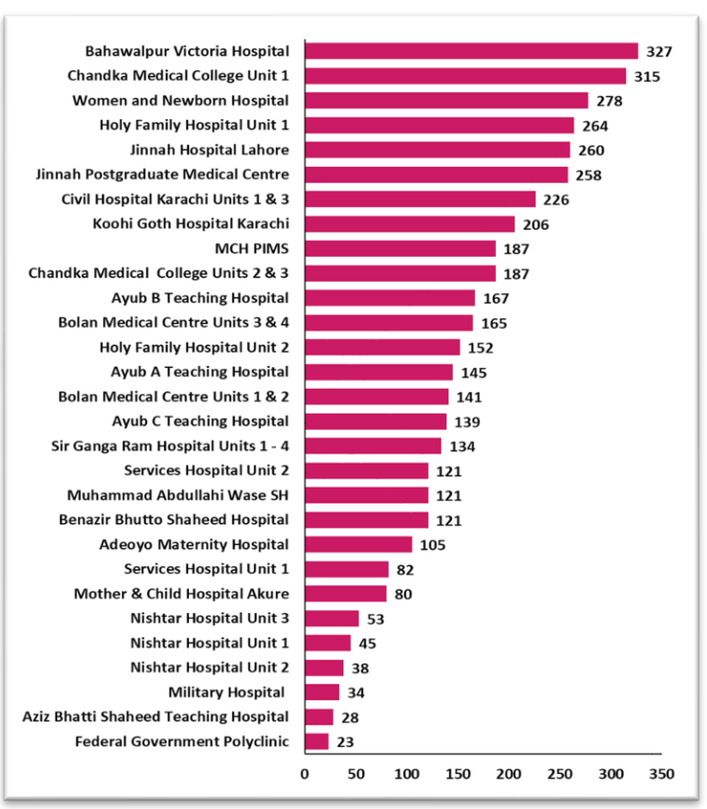
## On our way to finding better ways to treat women !!!

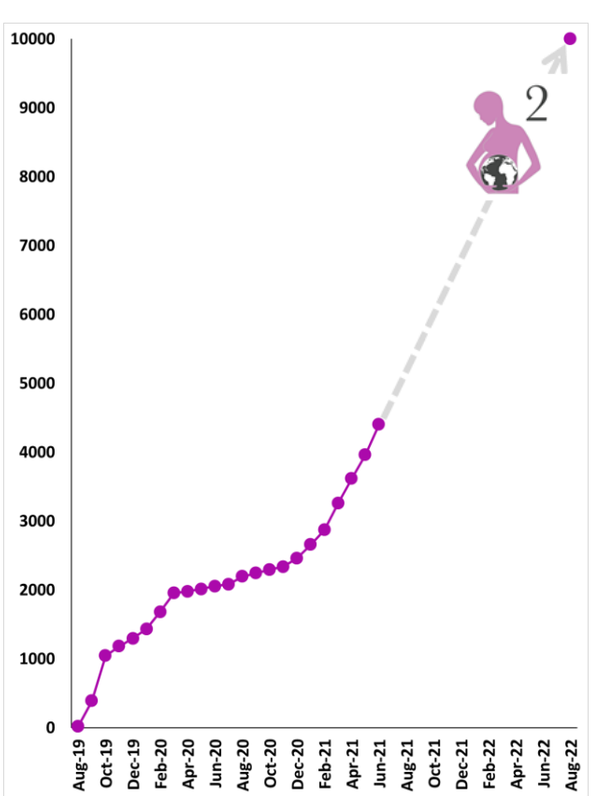
I am pleased to say that recruitment into the WOMAN-2 trial is back to pre-COVID-19 pandemic levels. A big thank you to collaborators in Pakistan for a fantastic restart after 9 months of total lockdown due to the pandemic and to teams in Zambia and Nigeria who have continued recruitment throughout. 1,940 women have been randomised already this year and we are well on our way to delivering the WOMAN-2 trial on time.

## Pakistan sites have randomised 3,818 women, which is over 85% of participants in the WOMAN-2 trial – BRAVO Team Pakistan!

Fantastic work by the team at **Bahawalpur Victoria Hospital,** who are the **No.1** recruiter with 327 women randomised to date

**Bolan Medical Centre, Units 1 – 4,** have recruited 306 women since they restarted the trial in February 2021 – the highest in 2021




A massive **THANK-YOU** to the brilliant teams at **Women and Newborn Hospital, Adeoyo Maternity Hospital** and **Mother & Child Hospital, Akure** for maintaining recruitment since they started the trial last year despite the COVID-19 pandemic.

Good Practice

# SITE SPOTLIGHT

**Mother & Child Health Centre - Pakistan Institute of Medical Sciences**

*'Alone we can do so little, together we can do so much'!*

**Research Fellows (L to R):**
Dr. Azka Zulfiqar, Dr. Zainab Asad, Dr. Quratulanne Maqbool

Good communication is vital for the trial to run smoothly and the team at **Mother & Child Health Centre - Pakistan Institute of Medical Sciences** have put in place **excellent communication** strategies! By sharing photos of each communication logbook entry in their site WhatsApp group, the whole team, including Principal Investigators and Focal People can have oversight of every woman in the trial at their hospital. We agree with the research fellows that working together is essential for the trial to succeed!

Is your team making use of the Communication Logbook?

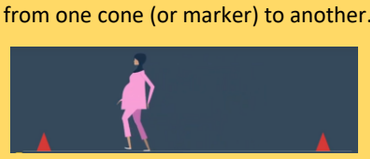
## Frequently Asked Questions

### CAN I USE MY HOSPITAL OR LOCAL LABORATORY HAEMOGLOBIN TEST RESULTS WHEN RECORDING HAEMOGLOBIN MEASUREMENTS FOR TRIAL PARTICIPANTS?

**No.** You must always use the Hemocue analyser to measure the baseline and post-delivery haemoglobin of potentially eligible women and trial participants. This is very important to ensure consistency across all trial sites. You should never guess or estimate a woman's haemoglobin.

### HOW CAN WE ACCURATELY RECORD A COMPLETE LENGTH IN THE SIX-MINUTE WALK TEST?

A woman has walked a complete length when she walks from one cone (or marker) to another.



Use a mark to indicate each complete length walked in the WOMAN-2 CRF booklet during the walk test to keep track of how many lengths have been completed. Remember, if at the end of 6 minutes a woman is part-way through a length, use the measuring tape provided to accurately measure this incomplete length so you can correctly calculate the total distance walked.

### SHOULD OUTCOMES DATA BE COLLECTED IF A WOMAN LEAVES HOSPITAL AGAINST MEDICAL ADVICE?

**Yes**. All outcomes data must be collected for women randomised into the trial. If a woman wishes to be discharged early, research fellows should engage the help of senior clinical team members to ensure that outcomes data is collected before the woman leaves hospital.

### WHICH BLOOD PRESSURE, HEART RATE AND RESPIRATORY RATE MEASUREMENTS SHOULD BE RECORDED IN OUTCOME FORM 1?

The **lowest** blood pressure within the **first** 24 hours after delivery and the associated heart and respiratory rates.

You should take into consideration **all** vital sign measurements recorded in this period (including those recorded by the research fellows and clinical team members).

Delivering woman2

## 10 key messages from the February and March 2021 Collaborator Meetings

### 10,000 women by August 2022

COVID-19 stopped us finishing recruitment by August 2021. Recruitment has now been extended - can we finish by August 2022?

### Teamwork makes the trial work

Both clinical and research team members must work together to ensure success. Principal Investigators (PIs) should ensure that everyone in their department is aware of the trial and their role in it.

### PI oversight is essential

The PI is responsible for ensuring that all procedures are carried out as per the trial protocol. They (or their Focal Person) should have weekly meetings with the Research Fellows to review data collected, screening, recruitment, & other trial activities.

### Communication is key

Most sites have set up WhatsApp groups with all trial team members to ensure good communication. You can ask the coordinating teams questions in this group. Use it to post messages to ensure that all eligible women are considered for the trial and that data collection occurs on time and is not missed.

### Refresher training sessions are essential

Anyone working on the trial must be trained and complete their GCP training. If you need a refresher on any trial topic or new staff trained, let LSHTM-CTU and the National Coordinating teams know.

### Recognition is a great motivator

Excellent contribution to the trial should be recognised. PIs should let LSHTM-CTU know of anyone who should get special recognition for their work. A certificate of contribution can be given or where appropriate they can be acknowledged in the trial publication.

### 24/7 Anaemia Screening

Anaemia screening MUST happen 24/7 to ensure all eligible women are enrolled in the trial. PIs should ensure that everything is in place so this can happen.

### Regular checks of trial equipment

Hemocue analysers, blood pressure monitors and other trial equipment should be checked frequently. Any concerns should be fed back to the trial coordinating team immediately, so they can be resolved.

### Trial data is continually reviewed at CTU

Data sent to us are subject to central monitoring. Relevant findings are fed back to site to improve procedures. It is also used to decide the haemoglobin level for trial inclusion at each site.

### The Trial Coordinating Team are here to help

Please contact your National Coordinating Team or LSHTM-CTU with any issues you may have or to share your experiences!