



Contact the WILL Team

Any queries?

Please contact us:

Professor Laura A. Magee
Chief Investigator
Laura.A.Magee@kcl.ac.uk

Sue Tohill (North)
Lead Research Midwife
Sue.Tohill@kcl.ac.uk
Mob: 07773970879

Julie Wade (South)
Lead Research Midwife
Julie.Wade@kcl.ac.uk
Mob: 07970338451

Katie Kirkham
Senior Trial Manager
WILL@trials.bham.ac.uk
Tel: 0121 415 9109
Temp no. 07974715467

Ruth Evans
Data Manager
WILL@trials.bham.ac.uk
Tel: 0121 415 9111
Temp no. 0121 293 8435

Clive Stubbs
Team Leader
WILL@trials.bham.ac.uk
Tel: 0121 415 9117

Birmingham
Clinical Trials Unit (BCTU)
Institute of
Applied Health Research
Public Health Building
University of Birmingham
Edgbaston, Birmingham
B15 2TT
Tel: 0121 415 9109

WILL Trial

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March is the start of new beginnings, the 1st day of Spring, month of daffodils, longer, brighter days as the clocks go forward and a time of celebration for all women; International Women's day and Mothers Day.

Site and participant update

As of 28th February 2021, we have **23** sites open and **142** randomised participants, **5** of whom were recruited in February 2021. Congratulations to:

- ◇ **Cwm Taf Morgannwg UHB** for consenting and randomising their **1st** participant
- ◇ **Croydon University Hospital, St Michael's Hospital Bristol, St Marys Maternity Unit Poole** and **Sunderland Royal Hospital** for consenting and randomising **1** participant each

This is fantastic, especially during these challenging times!

Welcome/Croeso to the teams at **Kings College Hospital NHS Foundation Trust, Cwm Taf Morgannwg UHB, New Cross Hospital** and **Southend University Hospital** who all opened to WILL in February. We hope to welcome more new sites soon.

Thank you...

...to all of our sites for your continued support and to all the women who have taken part in WILL so far. We have had **148** babies born to women who have taken part in WILL so we wish them all a ...



Positive feedback

We have received positive feedback from prior WILL participants. Please share with us any feedback you receive or add them to the WILL Twitter or Facebook page.

"Would like to thank all the team for letting me participate. Hope this helps other women going forward. Thanks for all your help"

"A very good trial"

"Happy to have participated in the Will study"

"Enjoyed being in the study as found it reassuring to be followed up regularly"

"Thank you for studying high blood pressure and for offering me to be a part of the trial."

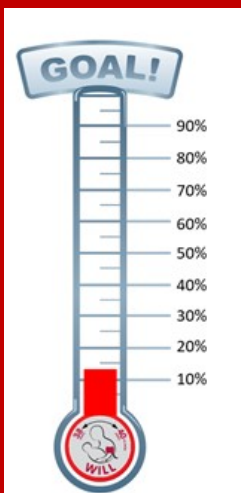
WILL Public Patient Involvement (PPI) group

We are looking for new members to join this group to help us review trial materials, trial progress, problem-solve barriers to recruitment. We plan to hold meetings 2-4 times a year (virtually at present). Please let us know of any women who are interested. They can either contact us, or if they are happy, you could pass on their details for us to contact them directly. We are very keen to hear their voices and make the experience of future WILL participants ever better.



Do you know of
any other famous
women named
WILL?

WILL target



Currently at
13% of our
randomised
target

International Women's Day: 8th March 2021

A global day celebrating the social, economic, cultural and political achievements of women. To also raise awareness about women's equality and gender parity. This year's theme is *Choose to Challenge* - raise a hand to show support.



<https://www.internationalwomensday.com/>
#IWD2021 #ChooseToChallenge

Famous female WILLs!

Some sites have had famous Williams to promote the WILL trial, but how many female WILLs can you think of? We found 3 to start us off:

Wil Van Gogh (*Wilhelmina/Willemina*): 16th March 1862 - 17th May 1941

Wil was a nurse and early feminist. Sister of Vincent Van Gogh. She also turned her hand at midwifery in January 1890 when she visited Paris and helped her other brother's wife with the birth of her first baby. Sadly, she was admitted to an asylum in 1902 where she stayed until her death almost 4 decades later.



Wilma Rudolph: 23rd June 1940 - 12th November 1994

An Olympic athlete who won gold medals in the 100m, 220m and 4x100m relay in 1960. She contracted polio at the age of 5 and needed to wear a leg brace until she was 12 years old. Overcoming this she went on to be known as the fastest woman in the world in the 1960s and became a role model for black and female athletes, causing gender barriers to be broken at previously all-male running events.



And last but not least...

Wilma Flintstone: 1959 - present

Born in 'Arkanstone', this strong-willed, level-headed cavewoman first made her appearance in 'The Flagstones', which soon became 'The Flintstones'. Married to Fred, mother to Pebbles and best friend to Betty, Wilma is a housewife, news reporter for Bedrock's local newspaper 'The Daily Granite' and a caterer (her specialty being 'gravelberry pie'). In her spare time, Wilma also enjoys volunteering for various charitable and women's organisations in Bedrock.



Facebook and Twitter pages



Our Facebook page is now open! Help us spread the word about WILL. Go have a look and please share and like!

[WILL Trial - Home | Facebook](#)



And don't forget our Twitter page @WillTrial - please follow, tweet and retweet!

Database queries

Thanks very much to all sites for addressing data queries during these challenging times when they are due. Please do continue to ...

- Run the *Active Data Queries* report on the database regularly to check for any new queries.
- Complete CRFs when they are due.
- Update screening forms for participants who were screened early once their GAs are within the eligibility window (36^{+0} to 37^{+6}), even if they don't meet other eligibility criteria. This helps the team to identify barriers to recruitment.
- Complete the *Reconfirmation of Eligibility and Randomisation* form for consented-only participants whilst they would still be eligible for recruitment, i.e. before they reach 38^{+0} . If you are unable to do so, there is a workaround that involves completing a hard copy of the form, scanning and sending to will@trials.bham.ac.uk so that Ruth can complete the form on the database on your behalf.
- Look out for the *Data Query Management* emails which may detail queries that cannot be raised directly on the database, e.g. queries on CRFs 2, 8 and 9
- Please get in touch if there are any queries about which you are unsure.

Thank you!

Information on this page will help you with any discussions you have with women and doctors/midwives caring for them about WILL.
We will feature a different topic each month. This month is:

Membrane Sweeps

Membrane sweeping is an intervention offered to hasten the onset of labour. However, membrane sweeps are not labelled as an official method of induction of labour in many UK hospitals.

There are no ongoing trials to inform practice in the UK, so should we be offering membrane sweeps or not?

NICE describes membrane sweeping as an adjunct to induction of labour rather than a method of induction of labour.


(NICE 2008)

Membrane sweeping compared to no treatment is more likely to result in labour onset and reduces the incidence of formal induction of labour (evidence of low certainty)

(COCHRANE 2020)

Membrane sweeping may cause vaginal bleeding and discomfort

(NICE 2008)



Membrane Sweeps

However, membrane sweeps compared to no treatment do not increase the chance of spontaneous vaginal birth.

(COCHRANE 2020)

Even though women acknowledged that membrane sweeps were uncomfortable, 88% would choose to have one in their next pregnancy.

(COCHRANE 2020)

There was also no difference in the risk of Caesarean birth between membrane sweeping and no treatment.

(COCHRANE 2020)

WILL and membrane sweeps

- If membrane sweeps are offered to women taking part in WILL and they accept, please enter this information on the database.
- In WILL, we collect the date of the first membrane sweep following randomisation and the number of times it has been performed. This will provide information about whether membrane sweeps had any impact on the start of labour.

True or False?

Q. If a membrane sweep is not possible due to not being able to enter the cervix, cervical massage may be used instead.

A. True. According to NICE guidance (CG70), if the cervix is not open enough to admit a finger, massaging around the cervix in the vaginal fornices may achieve a similar effect.

Topic for next newsletter: Induction of labour vs spontaneous labour





Emails and links:

Nhs.net email:
gst-tr.willtrial@nhs.net

WILL team at BCTU:
will@trials.bham.ac.uk

Website:
www.birmingham.ac.uk/WILL

Database:
Trials.bham.ac.uk/WILL

Test database:
Trials.bham.ac.uk/WILLTest



The WILL Team: who to contact

WILL at BCTU:

Randomisation challenges or telephone randomisation

Supplies/merchandise

SAE reporting

Database administrative issues, e.g. passwords

Payments for participants

Data queries

WILL Lead RMs:

Recruitment questions (eligibility, screening, etc.)

Clinical & protocol questions

Data form completion (including adjudication of maternal outcome page)

Data queries

Help talking to clinical staff



WILL monthly recruitment table Total as of 28th February 2021

4

C=Consented/ R=Randomised

	Jun - Dec 2019 (C/R)	Jan-Jun 2020* (C/R)	July -Dec 2020 (C/R)	Jan 2021 (C/R)	Feb 2021 (C/R)	Total (C/R)
Croydon University Hospital	3/3	6/6	10/9	1/1	1/1	21/20
St Mary's Maternity Unit Poole	4/4	6/6	8/6	1/1	1/1	20/18
Leicester Royal Infirmary	5/5	1/1	7/7	4/4	0/0	17/17
Leeds Teaching Hospitals	7/6	2/2	1/1	1/1	0/0	11/10
James Cook University Hospital	5/5	3/2	3/2	0/0	0/0	11/9
Liverpool Women's Hospital	6/6	1/1	3/3	0/0	0/0	10/10
St Mary's Manchester	4/4	3/3	2/2	0/0	†	9/9
Bradford Royal Infirmary	0/0	4/4	2/2 †	†	†	6/6
Singleton Hospital Swansea	1/1	2/2	2/2	0/0	0/0	5/5
Nottingham Queens Medical Centre	4/3	1/1	0/0	†	†	5/4
West Middlesex Hospital	3/3	1/1	0/0	0/0	0/0	4/4
St. Thomas' Hospital	3/3	1/1	0/0	†	0/0	4/4
Princess Anne Southampton	1/1	2/2	1/1	0/0	0/0	4/4
Royal United Hospital Bath	1/1	1/1	2/2	†	0/0	4/4
University Hospital of Wales Cardiff			3/3	1/0	0/0	4/3
North West Anglia NHS FT	1/1	2/2	**	**	**	3/3
Birmingham Women's Hospital	1/1	1/0	1/1	0/0	0/0	3/2
Nottingham City Hospital	2/0	1/1	0/0	†	†	3/1
Sunderland Royal Hospital	0/0	0/0	2/2	0/0	1/1	3/3
Great Western Hospital			0/0	2/1	0/0	2/1
York Teaching Hospital	1/1	0/0	0/0 †	†	†	1/1
Kingston Hospital			1/1	0/0	0/0	1/1
St Michael's Hospital Bristol			1/1	0/0	1/1	2/2
Cwm Taf Morgannwg UHB					1/1	1/1
Airedale General Hospital			0/0	0/0	0/0	0/0
Royal Berkshire Hospital			0/0	0/0	0/0	0/0
Western Sussex Hospitals			0/0	0/0	†	0/0
Kings College Hospital Trust					0/0	0/0
New Cross Hospital					0/0	0/0
Southend University Hospital					0/0	0/0
Total (C/R)	52/48	38/36	49/45	10/8	5/5	154/142

*The trial was paused from 20 Mar to 7 Jul 2020 for COVID-19

** Unable to restart WILL following COVID-19 pandemic

† Paused to WILL due to COVID-19 pandemic

WILL Trial Newsletter

Website: www.birmingham.ac.uk/WILL



Twitter: @WillTrial

