







PROMOTING INCLUSION AND DIVERSITY IN CLINICAL TRIALS: COVID-19

Professor Mahendra G Patel OBE PhD FHEA FIPA (India) FRPharmS

Pharmacy, and Inclusion and Diversity Lead: PRINCIPLE and PANORAMIC trials











OVERVIEW

- How pharmacy can support clinical trials in the community
- How clinical trials may be more representative of people from ethnic minority and underserved communities
- Understanding some of the challenges of engaging in trials
- How UK trials can help influence and or change practice internationally as well as nationally
- Extending learning from the PRINCIPLE trial to other trials







HEALTH INEQUALITIES

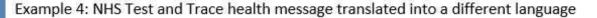














This is more accessible to South Asian communities but only if they can read in Urdu. Not all South Asian community members can read Urdu or English.



World Health Organization. Regional Office for Europe. (2020). Pandemic fatigue: reinvigorating the public to prevent COVID-19: policy considerations for Member States in the WHO European Region. World Health Organization. Regional Office for Europe. https://apps.who.int/iris/handle/10665/335820. License: CC BY-NC-SA 3.0 IGO

CLARITY IN MESSAGING

NHS TEST AND TRACE









PRINCIPLE TRIAL

The delivery of research studies in the pandemic have proven to be a significant challenge for many.

PRINCIPLE exploring re-purposed medicines for treatment of COVID-19 symptoms in the community stood out as the NIHR's flagship primary care COVID-19 study

Highlights importance of community outreach work (using the wider network of influence)

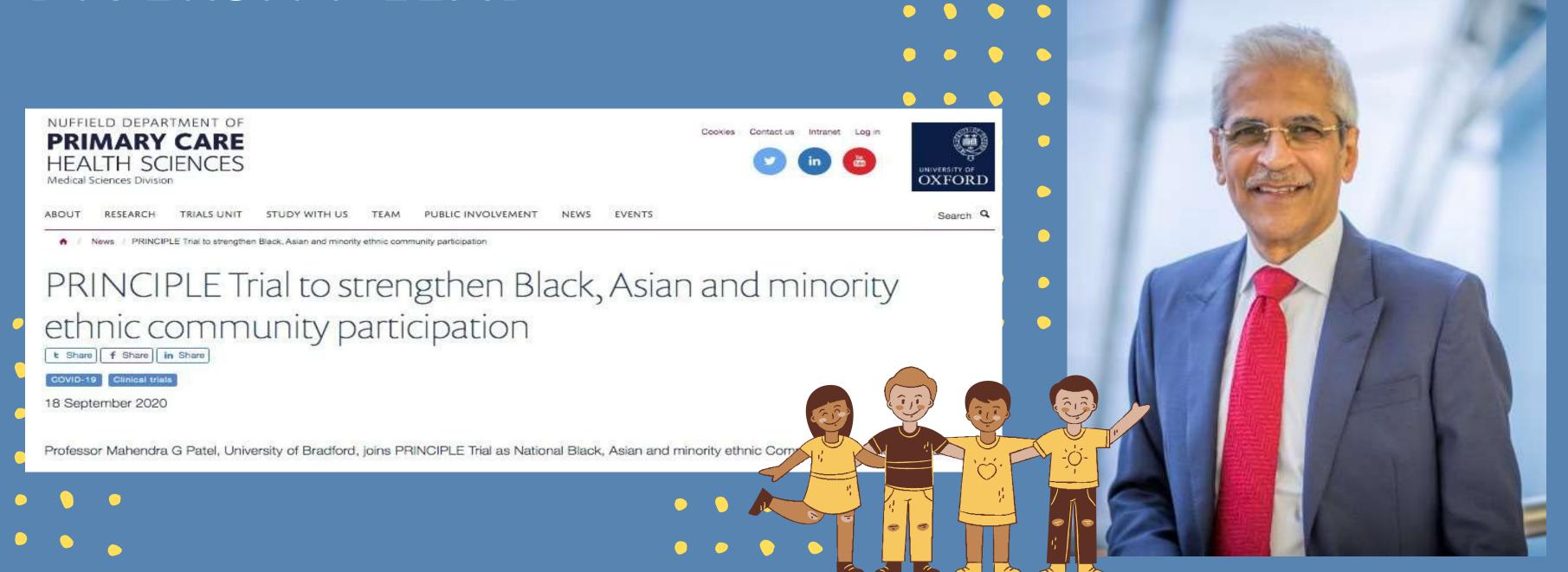
to help support recruitment and engagement in underserved and disadvantaged communities





APPOINTMENT OF INCLUSION AND

DIVERSITY LEAD









COMMUNITY OUTREACH: UK-WIDE COLLABORATION AND SUPPORT

University communities

Primary Care and NHS organisations

Medical, nursing, pharmacy, AHP, public health and community organisations

Research networks - NIHR CRNs

Charity organisations, faith groups, places of worship,

Local communities

Media – television, radio, print, social media

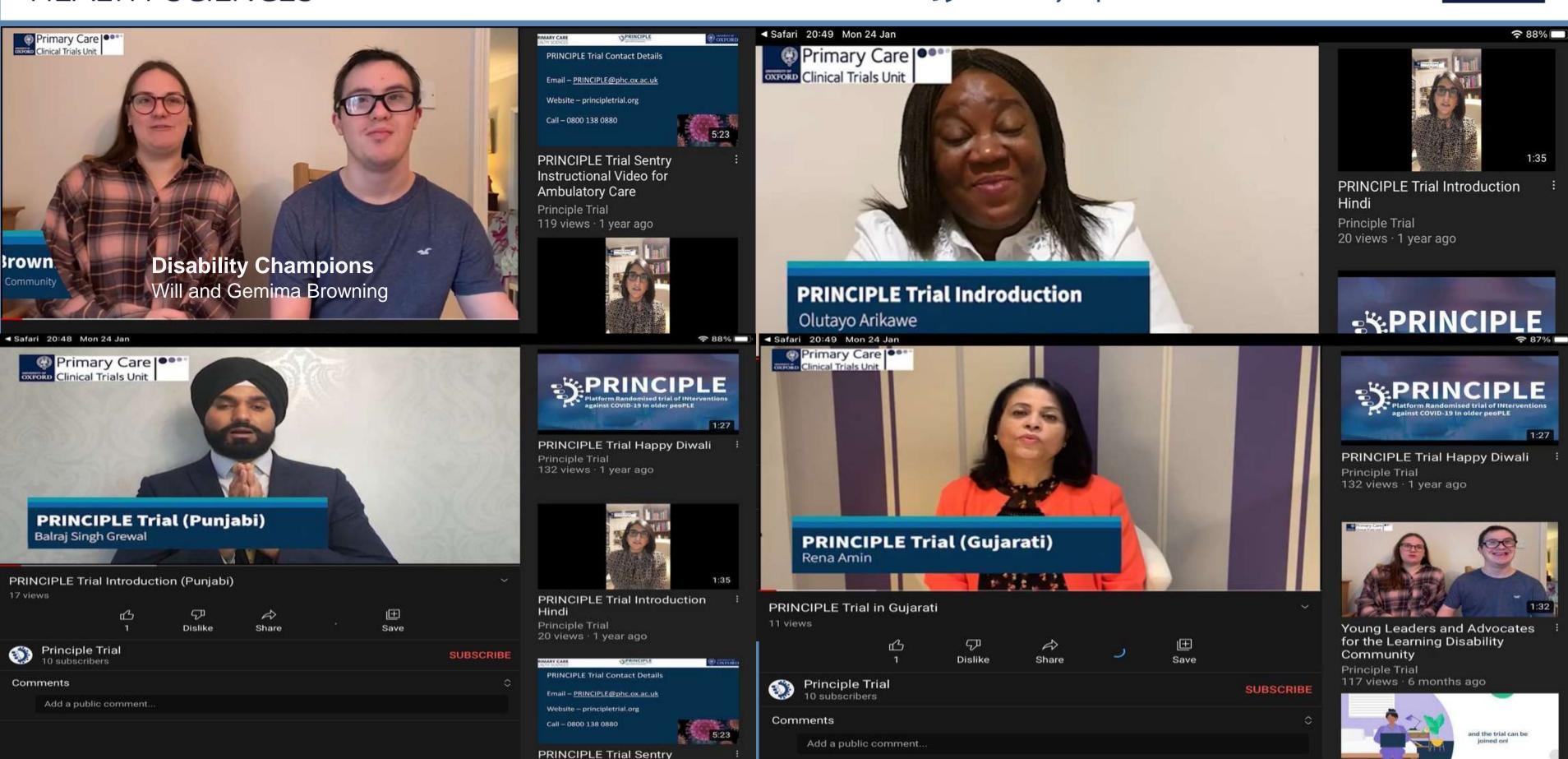




RESOURCES











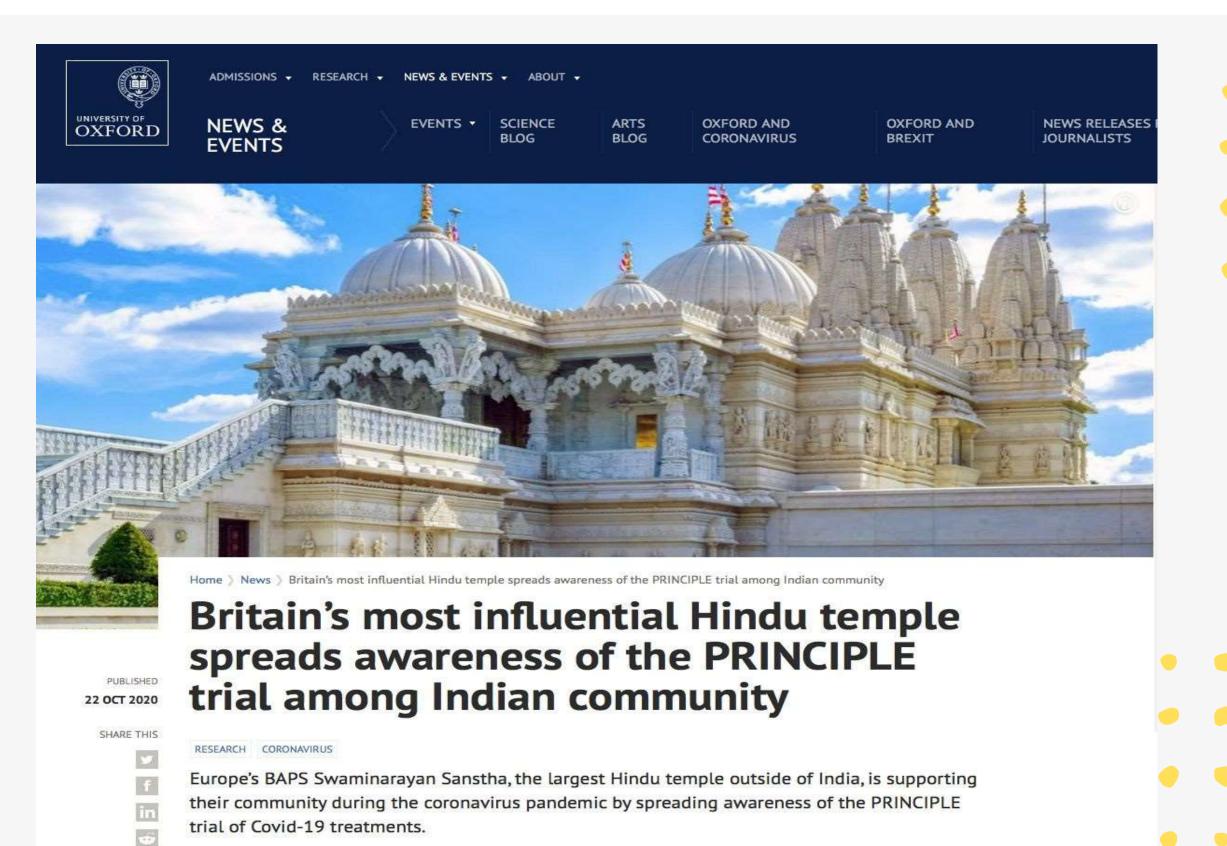


INFLUENCE OF PLACES OF WORSHIP

- Joined forces with a number of highly influential places of worship, such as the Neasdon
 Temple BAPS the most influential Hindu temple in Europe.
- Such places worked with us in promoting the messages via slide presentations displayed through the regular sermons from the temple.
- The Neasdon Temple BAPS has over 200,000 members alone in the UK.
- The information was also played on YouTube and on their own website.







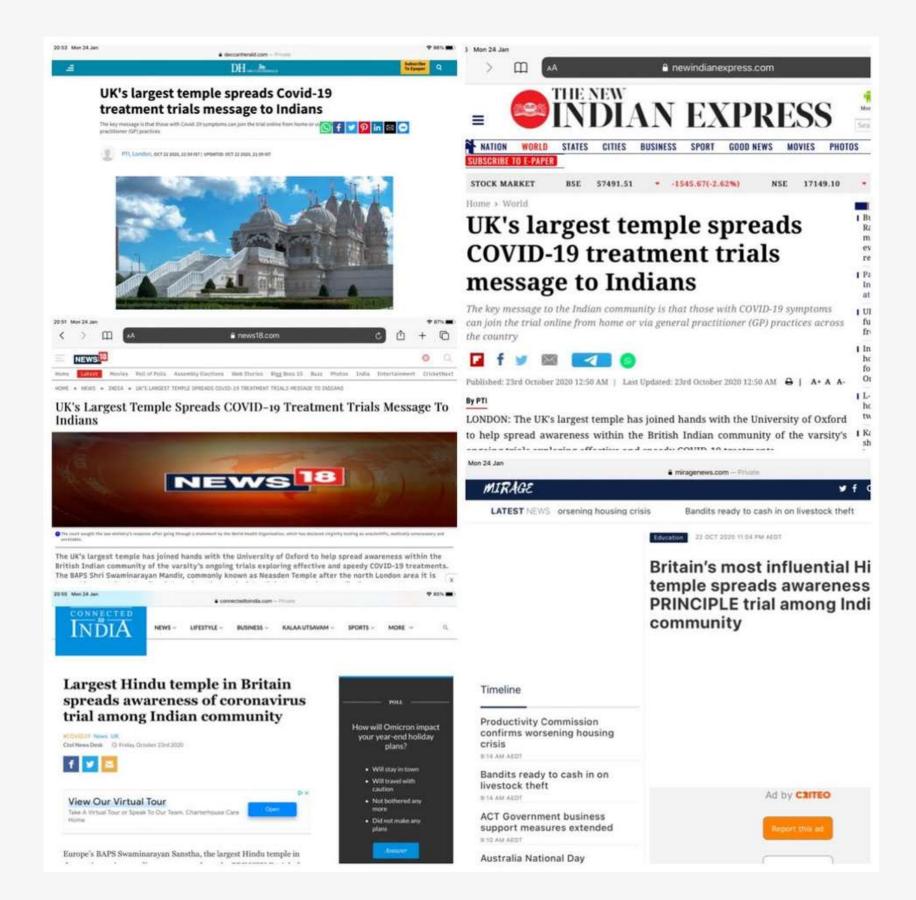


NUFFIELD DEPARTMENT OF

PRIMARY CARE HEALTH SCIENCES

















IMPACT: VISITS TO TRIAL WEBSITE OCT – NOV 2020





Three-fold increase on the 61 day average immediately following broadcast – and remained elevated





News

Bradford's Hindu community leaders on the vaccine



By Natasha Meek | > @journomeek











FAITH, community and tireless efforts to promote the vaccine has helped guide Bradford's Hindu community through the most "challenging" months of the pandemic.

In an interview held by the T&A and leading healthcare professional Dr Mahendra Patel, members of Bradford Hindu Council and priests gathered to reflect on the pandemic which has seen many loved ones lost to the

INFLUENCE OF FAITH

LEADERS

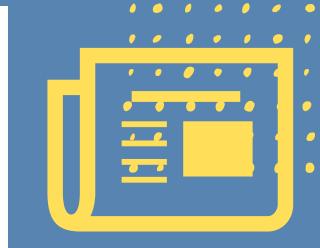
How faith is guiding Bradford's Hindu community in vaccine drive



His message was translated by Deepak who explained: "Scientists and doctors have been gifted with the talent of being able to save lives. In our [Hindu] scriptures a doctor or scientist, their job is to save lives not take lives so when a scientist steps forward we believe they have the power of God flowing through them.

"We take that as gospel. There's very few people who would turn round and not take that advice. We have to look after our villages, our towns, our societies. It's not down to one individual saying, 'I don't want to do this'.

"It's in our system, it's just like a moral obligation. He used a word called 'Dharma' - it's a given law or responsibility that you have to abide by."



Mahesh Mistry, the chairperson of Bradford Hindu Council, said they have been acting as a "funnel" for coronavirus updates.

"We've been asking round in our communities if there's anyone concerned about the vaccine or refusing to take it," he said.

"From our network, we don't know one family or person within the Hindu community that doesn't want to have the vaccine. They're probably crying out for the vaccine rather than the latter.







PHARMACY NETWORKS

- Using pharmacy networks and community pharmacies UK-wide to help reach out to people from all backgrounds
 - Includes the larger pharmacy national multiples as well as local pharmacy organisations displaying posters throughout the branches produced and disseminated at their **own cost**
- Additionally, reaching out to nationwide pharmacy networks across the four nations, Scotland, Wales, Northern Ireland, and England











USING THE PHARMACY INFRASTRUCTURE AND NETWORK

Oxford trial asks pharmacies to refer possible Covid patients

Pharmacy Magazine, 27 Oct 2020 (1) 1 Min Article



Community pharmacy teams are being asked to signpost patients to <u>PRINCIPLE</u>, a nationwide trial run by Oxford University.

REACHING OUT TO ALL FOUR UK NATIONS





CPS' Matt Barclay: Pharmacies can show their "vital role" in community healthcare

Community Pharmacy Scotland (CPS) is encouraging the 1,252 pharmacies in its network to signpost suitable patients to the Oxford University PRINCIPLE trial.















Subject: COVID-19 Knowledge and support sharing - Community Pharmacy Services 20/21

Date: 29th June 2021

Time Item Presenter(s)

19.30	Welcome, Introduction	Joe Brogan
19.35	Covid 19 - Northern Ireland Principle Trial University of Oxford	Professor Mahendra Patel









FUNDING AND STATISTICS

REGULATIONS AND IT DISPENSING AND SUPPLY SERVICES AND

THE HEALTH

CONTRACTORS AREA

COVID-19

The Health Landscape

About NHS Wales

Chief Medical Officer Updates

PRINCIPLE study in community pharmacy

The PRINCIPLE platform study is an UPH study to find treatments for COVID-19. It is now a UK wide study, and the only national priority platform trial in primary care. The study is designed to test a range of treatments in the community, with treatment arms that can be stopped, replaced or added easily, as evidence develops. PRINCIPLE is currently evaluating usual care alone versus usual care plus azithromycin; or usual care plus doxycycline. The study is being run by the University of Oxford and is funded by UK Research and Innovation and the Department for Health and Social Care through the National Institute for Health Research.



GP SITES RECRUITING

984 Practices signed up to assist with recruitment on PRINCIPLE

Other GP surgeries signed up to sign-post and direct to the trial team only







Green-lit surgery site map

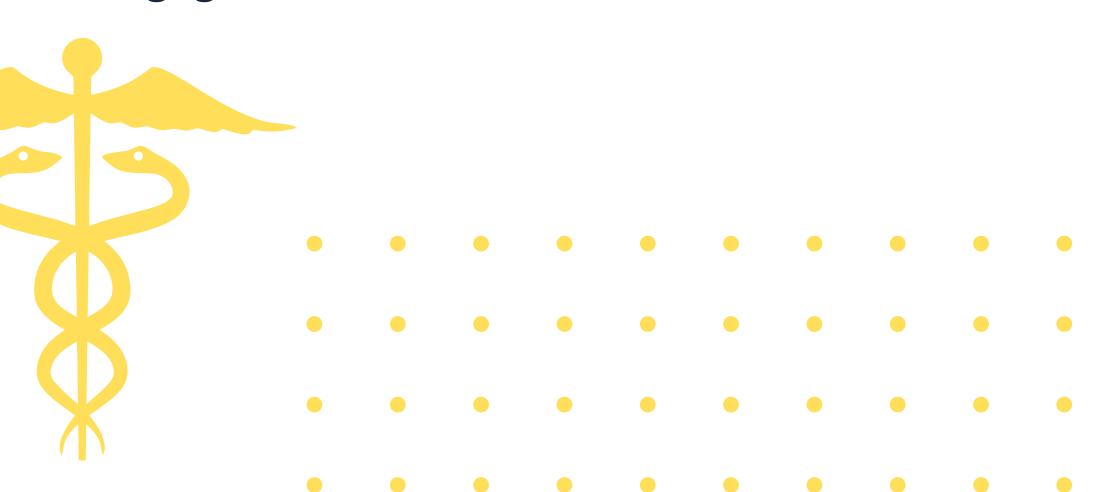






PHARMACY NETWORK

Circa 8000+ community pharmacies UKwide with footprints promoting engagement to PRINCIPLE











UNIVERSITY TOWNS AND CITIES

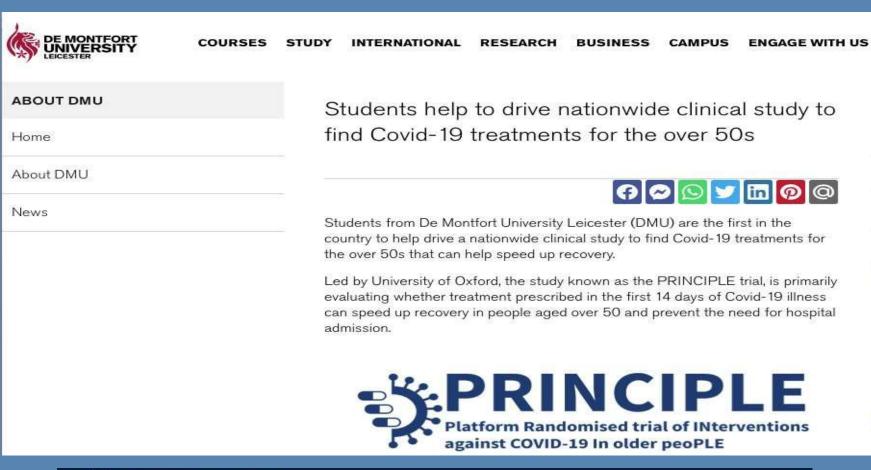
- Targeting university towns located in areas of high deprivation and communities of ethnically diverse backgrounds.
- University vice-chancellors working with us to promote the trials in their local communities through staff, students, their University websites with press coverage.

For example, working with the following places: Bradford, which has the largest proportion of people of Pakistani ethnic origin in England; Birmingham, which has one of the largest African and Caribbean populations in the UK; and Leicester, which has a diverse and concentrated population of South Asian communities

















UNIVERSITY STUDENTS

The University Of Bolton engaged in a three month initiative for students, trained by the Pharmacy, Inclusion and Diversity Lead, to go out into the community and share information about the trials.

Flyers, posters, leaflets, and videos were developed in a number of different languages and promoted in the university community, the local shopping malls, and vaccination centres.

Pop-up stands were displayed at these places, featuring students wearing hoodies showcasing both trials and identifying them as student advocates for the trials.

PRIMARY CARE

HEALTH SCIENCES















HOME

FOR PARTICIPANTS

FOR HEALTH & CARE PROFESSIONALS

NEWS

RESULTS

Search Q

OXFORD



For participants / Communities / Health and care professional organisations

Health and care professional organisations

Engaging health professionals

We are currently working with a variety of health professional organisations. These have been organised along, profession, specialism, religious or community lines. This variety again is key to ensure we are informing as wide an audience as possible.

These organisations are comprised of our front line health workers and are critical to raising awareness among health care professionals. These front line workers are the very people we want to keep most informed of our work. By doing this we intend to raise awareness across the entire community, including those most vulnerable to COVID-19.

ROYAL PHARMACEUTICAL SOCIETY







ROYAL PHARMACEUTICAL SOCIETY

DIABETIC SPECIALIST NURSES

GUILD OF HEALTHCARE PHARMACISTS

BRITISH ASSOCIATION OF PHYSICIANS OF INDIAN ORIGIN







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HOME FOR PARTICIPANTS

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WS RESU

RESULTS

↑ For participants / Communities / NHS and local government

NHS and Local Government

Working with clinical commissioning groups and local councils

The PRINCIPLE Trial with Professor Mahendra G Patel, have been working with regional and local NHS organisations and councils across the country.

This helps to reach both the health professionals and the general public in these areas, leading to increased awareness about the trial in areas that are being particularly hard hit by COVID-19.











BRADFORD CCG

MANCHESTER LPC

NORTH TYNE









GP SITES RECRUITING

984 Practices signed up to assist with recruitment on PRINCIPLE

Other GP surgeries signed up to sign-post and direct to the trial team only



Green-lit surgery site map







PHARMACY NETWORK

Circa 8000+ community pharmacies UKwide with footprints promoting engagement to PRINCIPLE





Map indicating pharmacy footprint

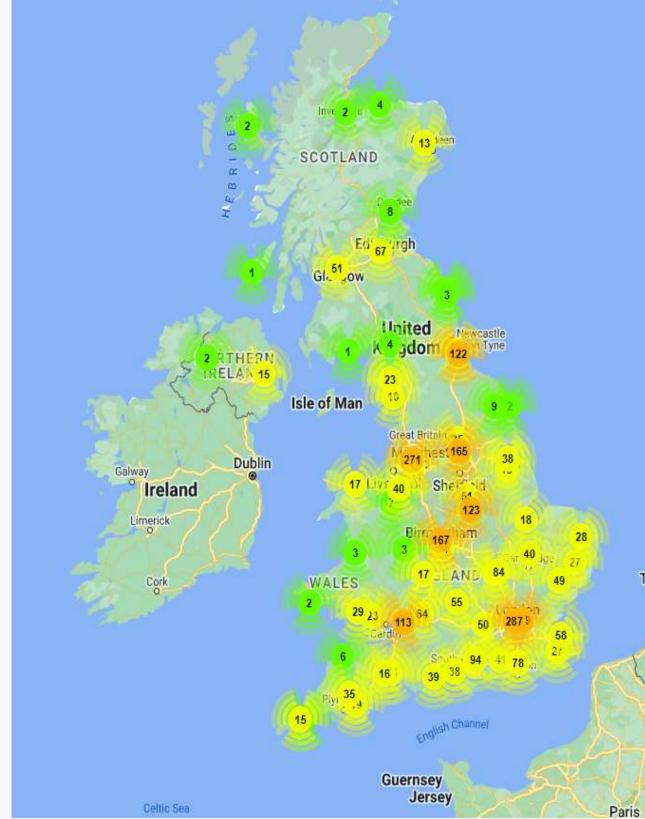




PRINCIPLE RECRUITMENT

GP sites mapped to recruitment UK-wide





Map: Recruiting surgeries

Cluster map: PRINCIPLE recruitment





OUTCOMES AND IMPACT



to be effective against

COVID-19 in patients

treated at home.



NHS

Department of Health & Social Care





CEM/CMO/2021/003

28 January 2021

PRINCIPLE selected to be a

national priority clinical trial

on COVID-19

Antimicrobials (azithromycin and doxycycline) Not Beneficial in the Management of COVID-19 (SARS-CoV-2) Positive Patients

Recommendation

It is recommended that:

Azithromycin should NOT be used in the management of confirmed or suspected COVID-19 infection either within primary care or in hospitalised patients, unless there are additional indications for which its use remains appropriate (see Product

Doxycycline should NOT be used in the management of confirmed or suspected COVID-19 infection within primary care, unless there are additional indications for which its use remains appropriate (see Product Details).







Colchicine shown not to improve

time to recovery in patients at

higher risk of complications with

COVID-19 in the community

COVID-19 Therapeutic Alert

10,000th recruit

joining the Trial

Inhaled budesonide is not currently being recommended as standard of care but can be considered (off-label) on a case-by-case basis for symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities, in line

Inhaled Budesonide for Adults (50 Years and Over) with COVID-19

After completing an interim analysis, the PRINCIPLE trial has reported that inhaled budesonide (800 micrograms taken twice daily, for up to 14 days) can reduce recovery time by a median of 3 days in symptomatic COVID-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities. A benefit in self-reported early sustained recovery at 28 days was also identified.

The analysis has not established whether budesonide can reduce hospital admissions or

The interim results from PRINCIPLE build on the findings of the STOIC trial Phase II study on inhaled budesonide. This study suggests that early administration of inhaled budesonide reduces the likelihood of needing urgent medical care and reduces time to recovery following early COVID-19 infection.

















THE LANCET

Log in





CORRESPONDENCE | VOLUME 397, ISSUE 10291, P2251-2252, JUNE 12, 2021

Inclusion and diversity in the PRINCIPLE trial

Mahendra G Patel 。 Jienchi Dorward 。 Ly-Mee Yu

FD Richard Hobbs - Christopher C Butler 🖾 - on behalf

of the PRINCIPLE Trial Collaborative Group

Published: June 12, 2021

DOI: https://doi.org/10.1016/S0140-6736(21)00945-4

PlumX Metrics

COMPARABLE TO NATIONAL CENSUS

This strategy contributed to the inclusion of 55 (4.0%) South Asian and seven (0.5%) Black participants in our analysis of azithromycin for treatment of suspected COVID-19,2 which was comparable to 3.7% Asian ethnicity and 1.6% Black ethnicity among people older than 50 years (PRINCIPLE's target age group) in England and Wales.3 The proportions of participants' in Index of Multiple Deprivation (IMD) quintiles were (from most to least socioeconomically deprived): 352 (26%) of 1375 in IMD1; 267 (19%) of 1375 in IMD2; 270 (20%) of 1375 in IMD3; 241 (18%) of 1375 in IMD4, and 245 (17%) of 1375 in IMD5. Overall, this shows good recruitment from socioeconomically deprived and minority ethnic communities.

PRINCIPLE's innovative approach now supports the recruitment of minority ethnic participants to other UK national trials. We recognise that



August NIHR Learn Insights



Welcome

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NIHR Learn Insights CPD resource



How can we effectively engage diverse communities into research?; Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses (PRINCIPLE Trial)



Prof Mahendra Patel
PRINCIPLE Trial
-investigator, and Pharmacy and E

Co-investigator, and Pharmacy and Ethnic Minority
Communities Research Lead







SUMMARY: DIVERSITY AND INCLUSION

- Overall good recruitment from socioeconomically deprived and ethnic minority communities comparable to national census data
- Pharmacy contributing to wider recruitment
- Inclusion of 4.0% of SAs in our analysis of azithromycin for treating suspected COVID-19 comparing well to 3.7% SA ethnicity
- Proportions of participants' in Index of Multiple Deprivation (IMD) quintiles were (from most to least socioeconomically deprived): 352 (26%) of 1375 in IMD1; 267 (19%) of 1375 in IMD2; 270 (20%) of 1375 in IMD3; 241 (18%) of 1375 in IMD4, and 245 (17%) of 1375 in IMD5.
- Pharmacy has helped reach out to range of diverse communities and to areas of high deprivation traditionally poorly represented in research

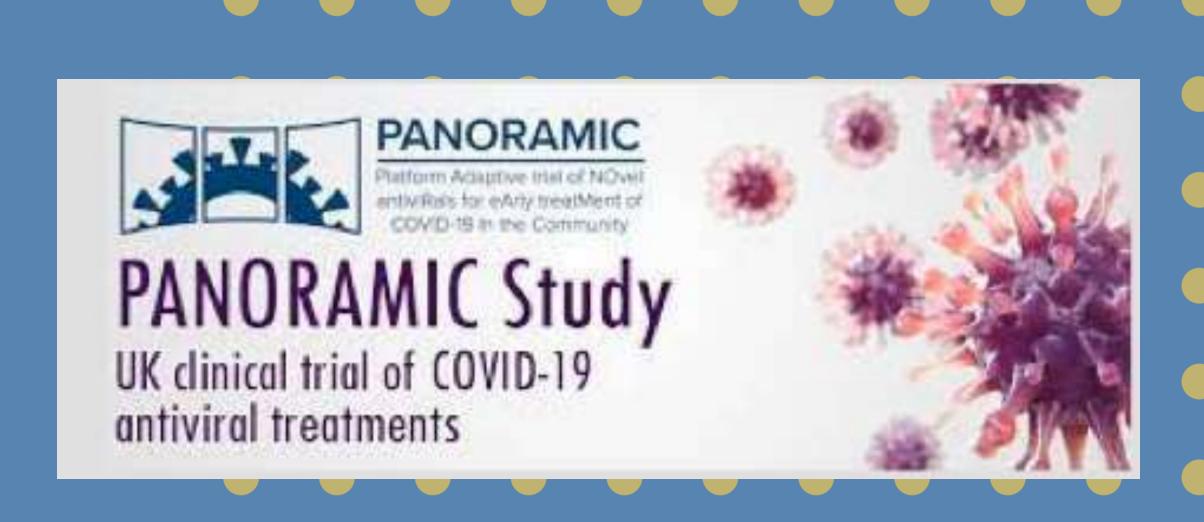






PANORAMIC

- Investigating novel
 and licensed antivirals
 Study opened
- 8 December 2021



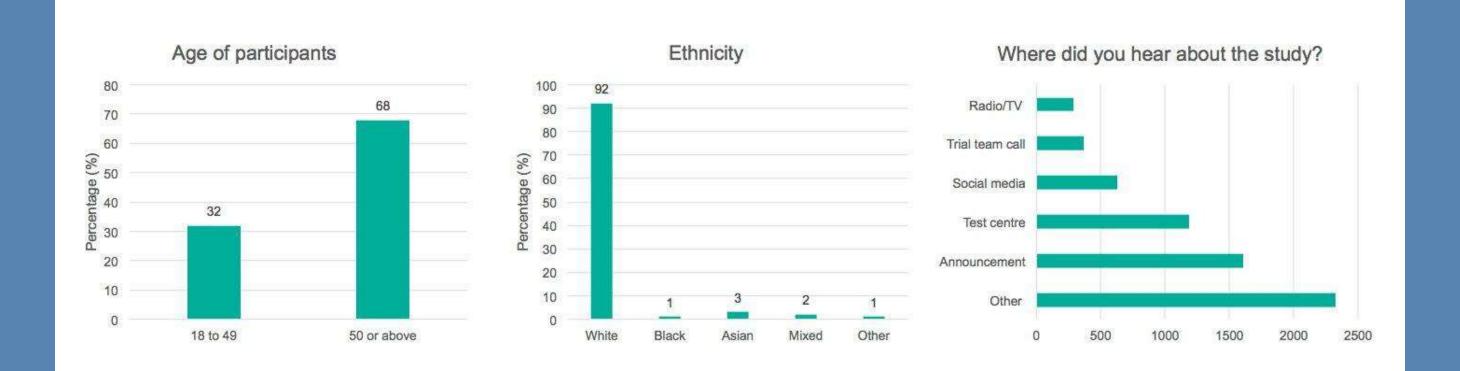






PANORAMIC Update

Patient Demographic information (patients screened: 15,210, patients recruited: 2,564)









DHSC WEBINARS JAN/FEB

Senior Cabinet Office staff and ministers supported by hosting four high-level interactive webinars – w/c 31 Jan 2022

- Chaired by the Pharmacy, and Inclusion and Diversity Lead
- Aimed at pharmacists, nurses, doctors, and the public health community
- Reaching out to Wales, Scotland, Northern Ireland, and England











PANORAMIC RESOURCES





PANORAMIC RECRUITMENT FLYER

To personalise and insert own organisation logo at bottom





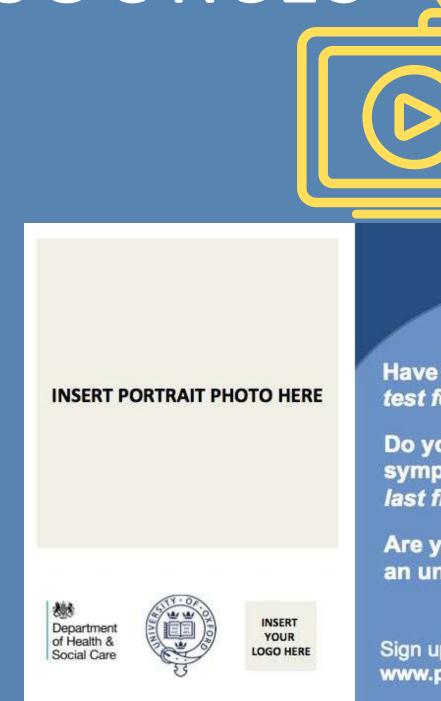


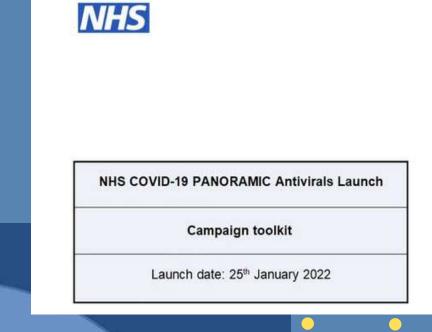
VIDEO SCRIPT:

Intro: I am Mr/Miss/ Dr/ Prof etc XXXX from name of ORGANISATION or practice

COVID-19 has affected the lives of everybody. We need to find safe and effective treatments that can help people to recover at home, without the need to go to hospital.

Researchers at the University of Oxford are trying to do this right now, and you have an opportunity to help.





Have you received a positive test for COVID-19?

Do you feel unwell with symptoms that started in the last five days?

Are you over 50, or 18-49 with an underlying health condition?



Sign up now at www.panoramictrial.org







EXAMPLES OF OUTPUTS







DOCTOR ORGANISATIONS









PANORAMIC is now CPD accredited!











MUSLIM DOCTORS CYMRU

Muslim doctors Cymru helped prepare various materials in different languages, which were then promoted to communities in Wales and wider.











MEDICAL SCIENCE WITH FAITH





Post-Jummah Announcement



Finding new effective antiviral treatments for COVID-19

Assalaam'alaikum dear brothers and sisters,

Allah says in the Quran "whoever saved one life, it is as if they saved
the whole of humanity" 5:32

There is a study taking place in Oxford which is seeking to find cures - not vaccines, but actual treatments - for COVID

They have participants from all backgrounds but need more Muslims to take part and support the study

The trial is UK-wide and led by the University of Oxford

IF you have pre-existing health condition have COVID positive test in the last 5 days AND having symptoms

Visit www.panoramictrial.org and help be part of world leading research which may save the world.











The Muslim Council of Britain

British Muslim organisations support PANORAMIC ahead of Ramadan

31 March 2022

The Muslim Council of Britain (MCB) and the British Islamic Medical Association (BIMA) joined forces in March to help promote the PANORAMIC trial as part of a series of outreach activities ahead of the Muslim holy month of Ramadan, enabling greater outreach to diverse communities across Britain.





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- colleagues,
- AHPs, and health
- charities





Social Care













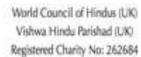






















BIRMINGHAM CITY
University

























Dr Nasibu Mwande, Specialty Doctor, Emergency Medicine lantania UK Reuthcare Diagona Assantanian (TUREDA) Wite-Char











STUDENT ADVOCATES (II)

Student Champions from the University of Bolton who have helped to recruit volunteers through community outreach work for the world's largest trials to treat Covid-19 have been congratulated for their hard work.













NURSES AND NATIONAL NURSING ORGANISATIONS



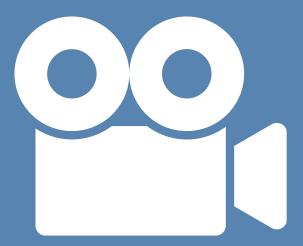




NATIONAL CHIEF NHS OFFICERS

The UK Government's Chief Nursing Officer for Wales produced videos to share through their networks and their countries, and encouraging their counterparts to do same.

Likewise, with the Chief Pharmaceutical Officer for NHSE & I









REGULATORS: PHARMACY

Gaining the support from the pharmacy regulatory body to help promote the trial through their own website to all the registrants within the profession – one of the first of its kind.











Pharmaceutical

Regulate a Search Regulate

PANORAMIC study: help find effective early treatments for COVID-19

We're raising awareness about PANORAMIC - a UK-wide clinical study looking at new antiviral treatments for COVID-19, to help make sure everyone has the opportunity to take part in the trial

The Covid-19 pandemic has undoubtedly exacerbated and further exposed the scope and scale of inequalities in society and in healthcare outcomes.

Through our new strategy Delivering equality, improving diversity and fostering inclusion P, we have committed to tackling discrimination and supporting the reduction of health inequalities through the work that we do, as well as using our influence to support or work with other stakeholders to do this.

We're taking this opportunity to raise awareness about PANORAMIC - a UK-wide national priority clinical study, to find out how effective new antiviral treatments are in the UK population, so that the NHS can develop plans for making these treatments more widely available to people who would benefit from them the most, by getting better sooner and reducing the need for hospitalisation.

The UK's medicines regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), is the first in the world to approve an antiviral agent for the treatment of early symptoms of COVID-19, and it is also approved by the Health Research Authority.

Article Feed On average, about **500,000** visits to the GPhC website each month

Total registrants as at 1 January 2022 - 85,506 (Regulate sent to everyone who opts in)

We promoted the **PANORAMIC study** through our website, our Regulate newsletter and through our **Twitter** pages

3,703 views of Regulate between 16 February and 16 March 2022



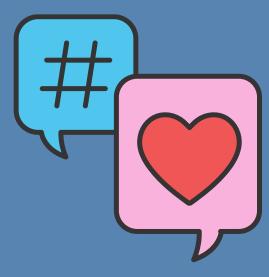




KEYINFLUENCERS

Working with key individuals having established audiences to reach tens of thousands of people over social media.

For example, Lady Anne Welch held an informative live Instagram interview, sharing news of the trials to her audience, most of whom are from Black and ethnic minority communities.





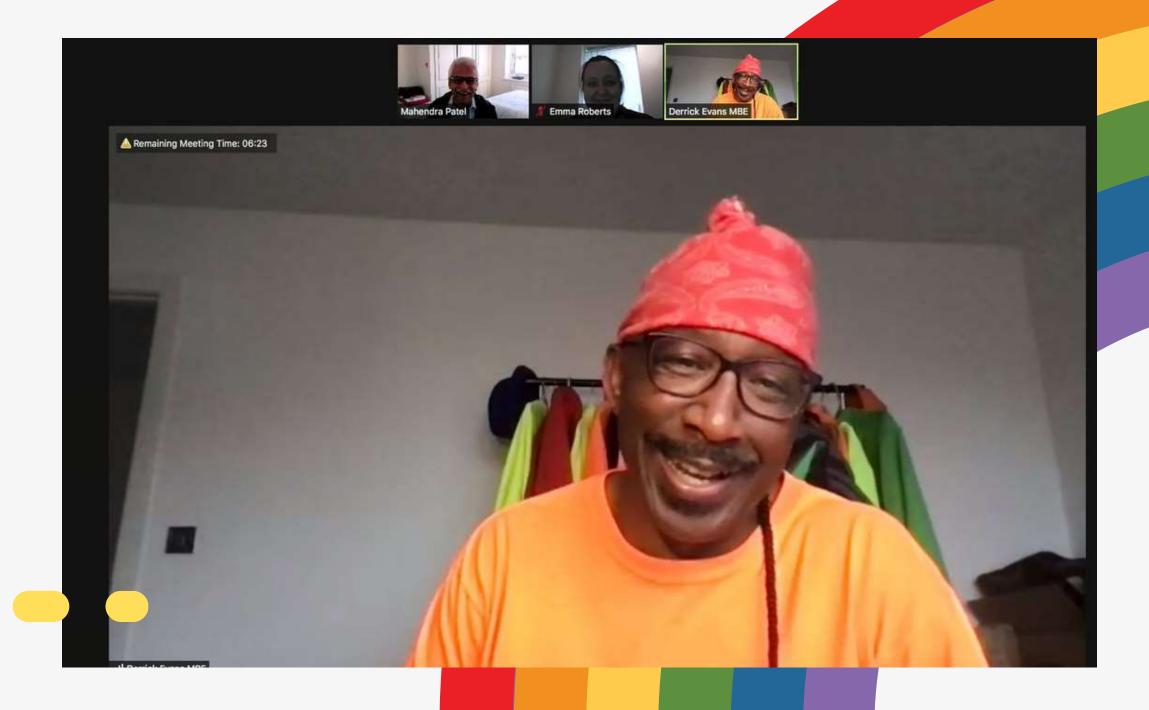






CELEBRITIES: MR MOTIVATOR!





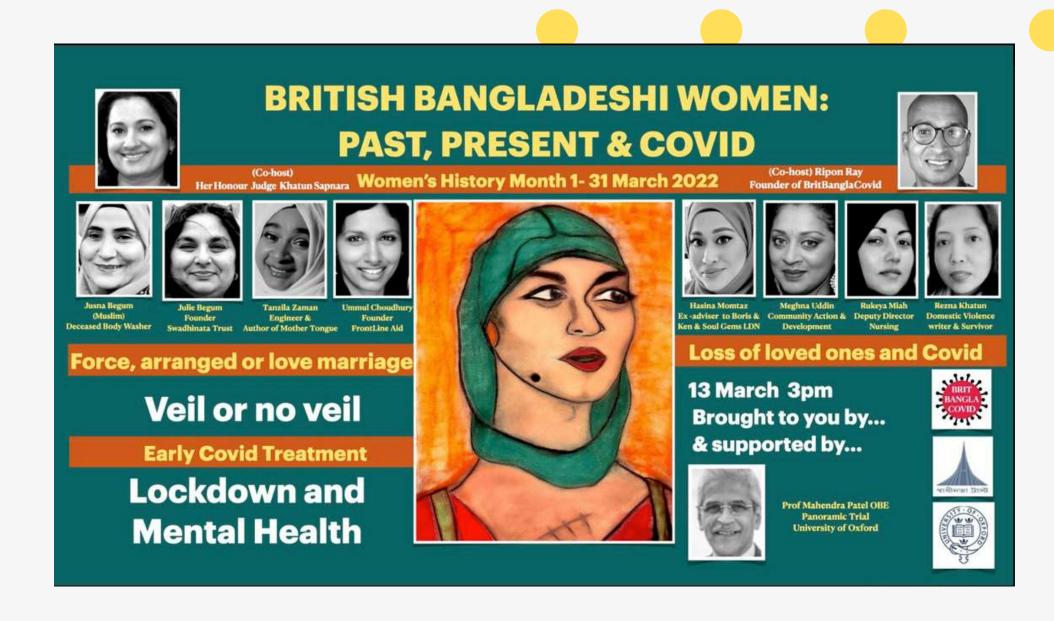






WORLD WOMEN'S DAY WEBINARS

Reached out to Bangladeshi communities and the Nepalese communities – graced with representation by High Commission Offices









PARTNERING WITH THE LARGEST SOUTH ASIAN MEDIA COMPANY IN UK

Gaining the support of Asian Media Group, the largest South Asian media company in the UK to help reach out to the South Asian communities in raising the awareness of the trials.













Hazel Kirwin @H... · 26/01/2022 ··· Please consider signing up to the @PANORAMICTrial

CALL FOR CASE EXAMPLES

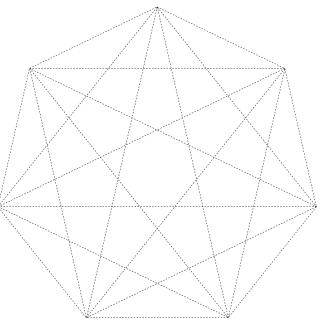
It couldn't be easier!!

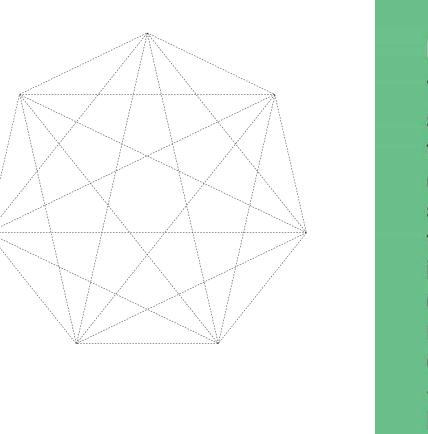
gov.uk/government/new... @drmahendrapatel

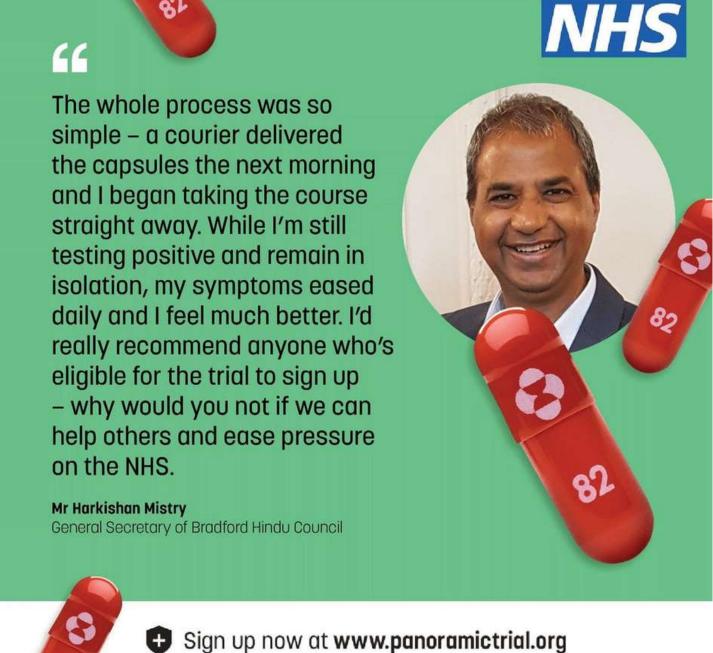
" I'd really recommend anyone who's eligible for the trial to sign up - why would you not if we can help others and ease pressure on the NHS."

Hazel, a pharmacist from Whitley Bay, got COVID-19 early in January and so signed up to the trial immediately to help find antiviral medicines to treat the virus. Hazel said:

- " I enrolled online when I got COVID-19 and the process was really simple. I got a call from a nurse right away who took me through everything and since then I've just had to keep a short online daily diary which takes less than a minute to do.
- "The process really couldn't be simpler, and it's so exciting to be part of this world leading effort to find a treatment for COVID-19.
- Both as someone who got COVID-19 and as a pharmacist, I know the damage this virus can do and would urge anyone eligible to visit the website and really consider getting involved as it could save lives."















CREATING HISTORY

The fastest and the largest recruiting primary care clinical trial – in the world

Over 20,000 of you have stepped forward to help find community-based treatments for acute COVID-19



We couldn't have done this without you

The PANORAMIC study aims to find antiviral treatments to improve symptoms early and reduce hospital admissions for people with COVID-19.





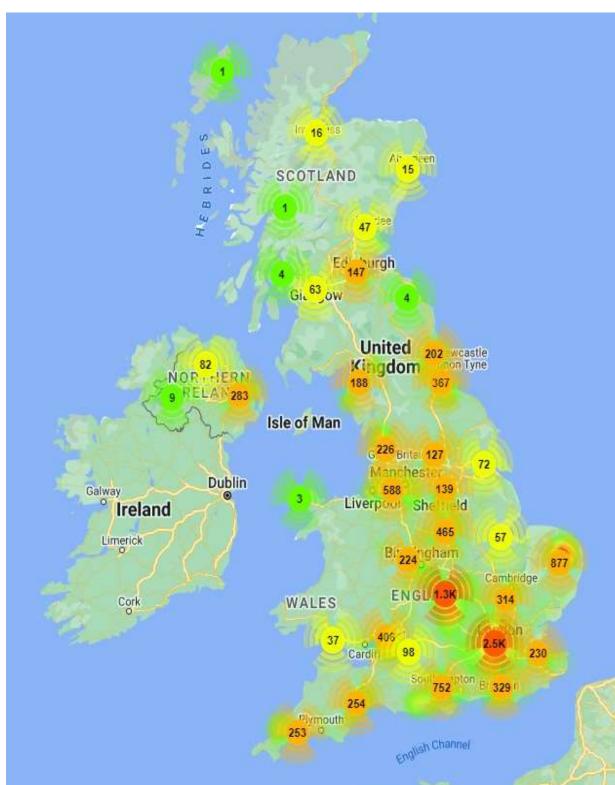


RECRUITMENT MAP

Displaying the scale and reach of recruitment within the first FOUR months



Each point shows GP Site with at least one participant



Cluster map: showing recruitment numbers

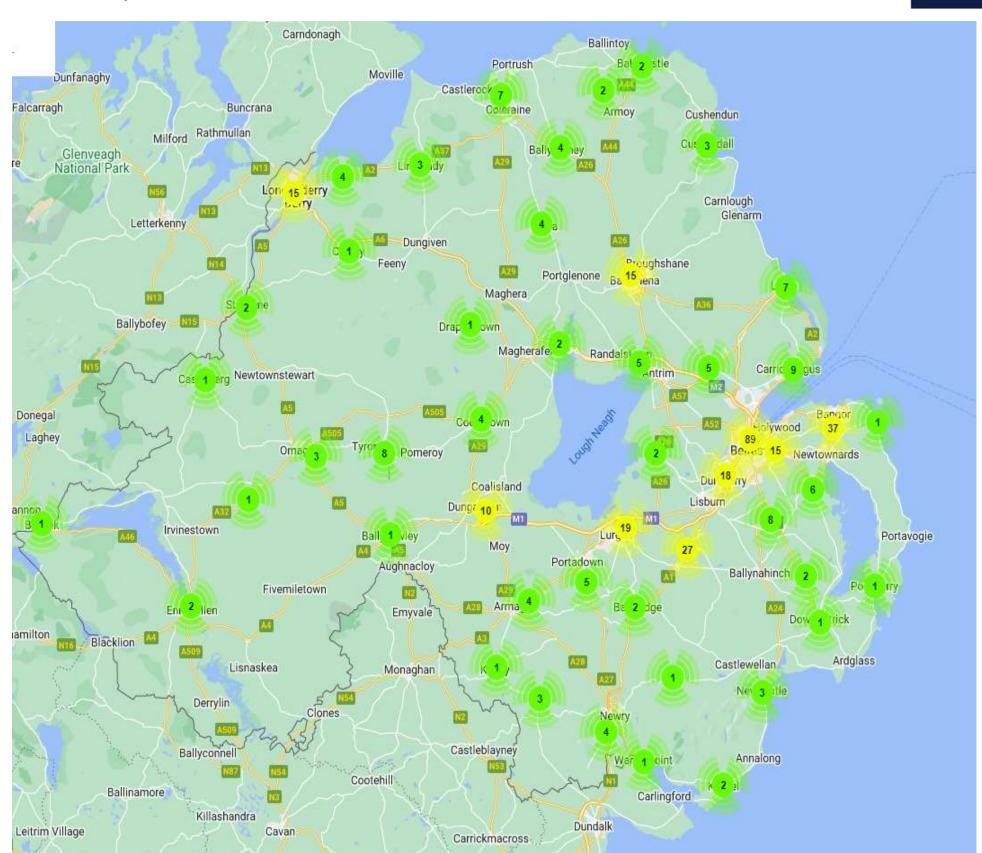






NORTHERN IRELAND

Historically, it has been tougher to engage with practices across the devolved nations



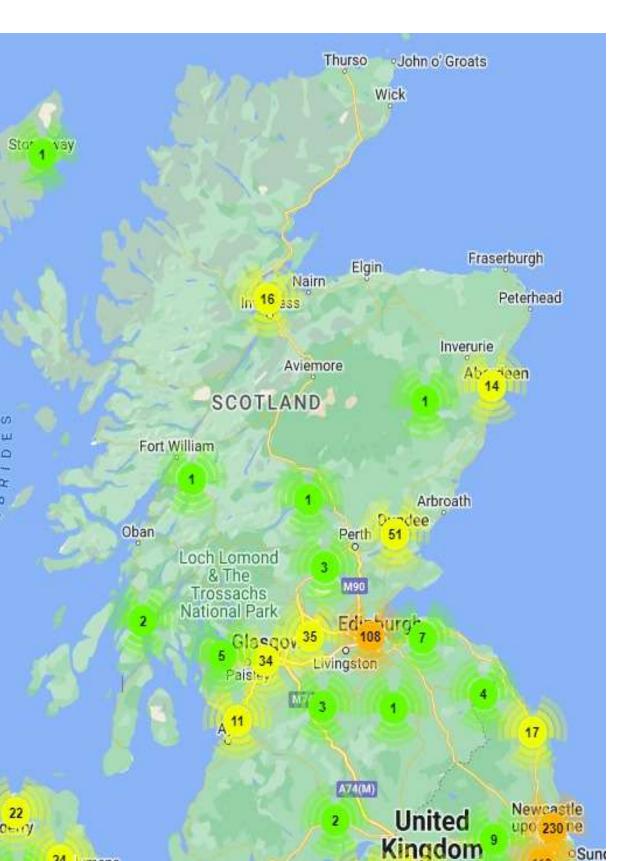
Cluster map: showing recruitment numbers in Northern Ireland

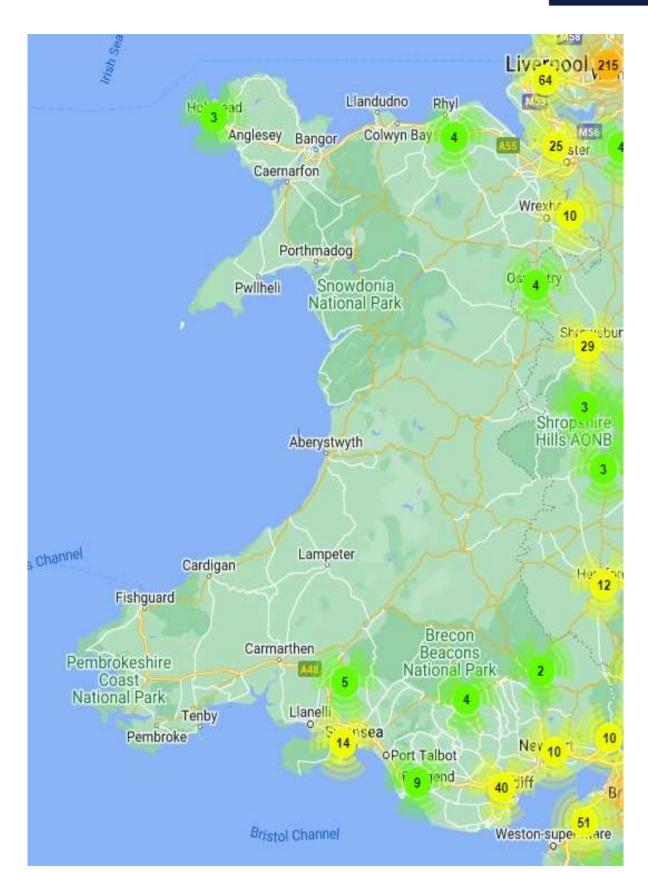
PRIMARY CARE HEALTH SCIENCES

SCOTLAND AND WALES

A closer look at current recruitment in the devolved nations







Cluster map: showing recruitment numbers in NI

Cluster map: showing recruitment numbers in Wales









PHARMACY NETWORK

Showcasing the different stage and progression of the Pharmacy Network across the UK.

Even this struggles to cover the support provided with over 8000 sites signed up to help signpost.













BARRIERS

- Goodwill has limited life
- Lack of dedicated investment and support
- Establishing sustainable, long term, relationships of trust with organisations and their leaders – not just one-offs
- Creating a sense of belonging and urgency
 - Limitations of trial team / site team









SUMMARY AND LEARNINGS

Pharmacy plays vital role in supporting future clinical trials and helping to achieve many historical milestones

Uniquely working with cabinet and senior government office staff.

- Pharmacy staging at the world's leading university and research centre –
 Nuffield Department of Primary Care University of Oxford
- Science and faith combining together at this level HISTORIC
- Gaining support from regulators (GPhC) FIRST of its kind
- University students engaging in community outreach work
- One size doesn't fit all

Future considerations: Cost analysis of largely goodwill-based strategy? Carbon footprint? Sustainability?









THANK YOU – LET'S ALL MAKE A DIFFERENCE TOGETHER



@dr.mahendrapatel @drmahendrapatel



mahendra.patel@phc.ox.ac.uk

