

Impact of COVID-19 on Trial Methodology

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Introduction

- Covid 19 pandemic has demonstrated the strength, resilience and expertise of the UK's health research system
- UK has led the world in tackling covid, conducting trials and communicating outcomes in record time

RECOVERY
Randomised Evaluation of COVID-19 Therapy

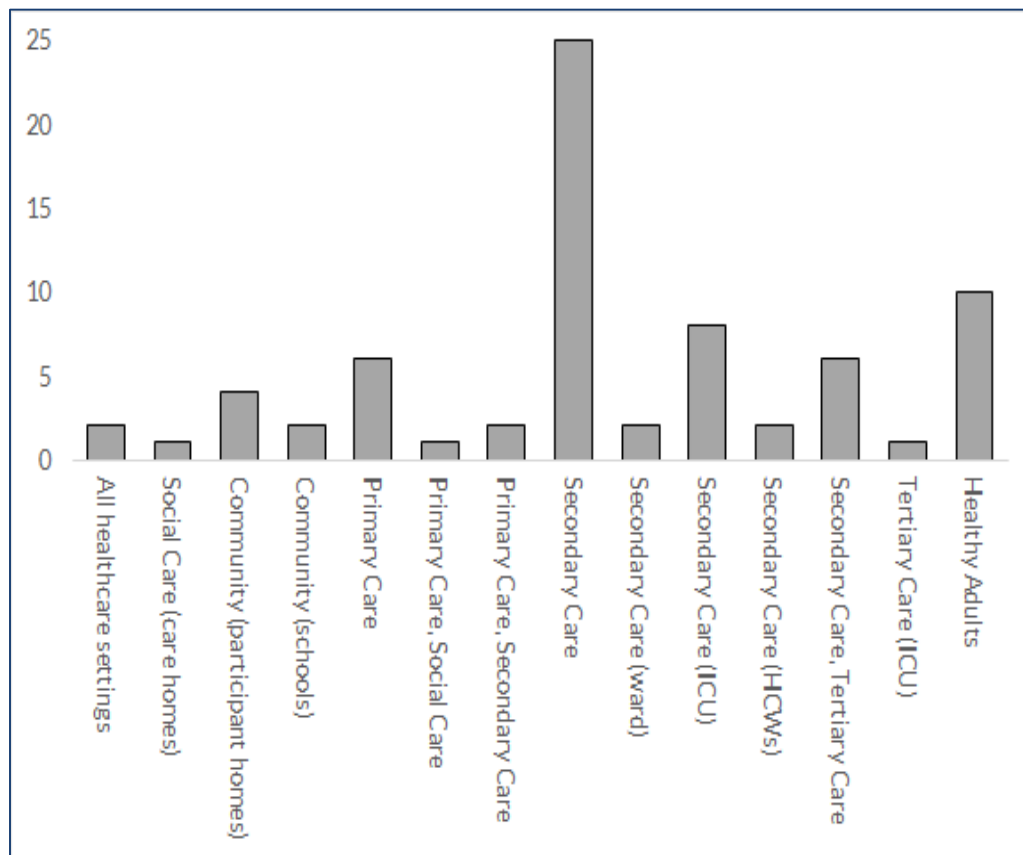
98 days from first draft protocol to adoption of 1st proven therapy

THE LANCET
Lopinavir-ritonavir in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial
RECOVERY Collaborative Group*

THE NEW ENGLAND JOURNAL of MEDICINE
ORIGINAL ARTICLE
Effect of Hydroxychloroquine in Hospitalized Patients with Covid-19
The RECOVERY Collaborative Group*

NIHR Urgent Public Health Covid Portfolio: (72 trials, 564,078 patients)

Study Setting



	No. of Studies	%
All healthcare settings	2	3%
Social Care (care homes)	1	1.5%
Community (participant homes)	4	5.5%
Community (schools)	2	3%
Primary Care	6	8%
Primary Care, Social Care	1	1.5%
Primary Care, Secondary Care	2	3%
Secondary Care	25	35%
Secondary Care (ward)	2	3%
Secondary Care (ICU)	8	11%
Secondary Care (HCWs)	2	3%
Secondary Care, Tertiary Care	6	8%
Tertiary Care (ICU)	1	1.5%
Healthy Adults	10	14%
Total	72*	-

*this is the most up to date number of nationally prioritised COVID-19 studies

Data Collated: 12 November 2020

Lessons Learned

Based on

- Membership and findings of NIHR Urgent Public Health Group
- Membership and findings of UK Clinical Research Coalition
- Membership and findings of NIHR Restart Advisory Committee

However views my own

Key areas

- Embracing technology
- Efficient trial design
- Engaging patients and the public
- Addressing inequalities

Embracing technology

Technology enabled delivery of healthcare

E trials

- Connected home devices
- Social media
- E consent
- Electronic CRF
 - Health data enabled trial platforms

Use of AI/Machine Learning



Efficient Trial Design

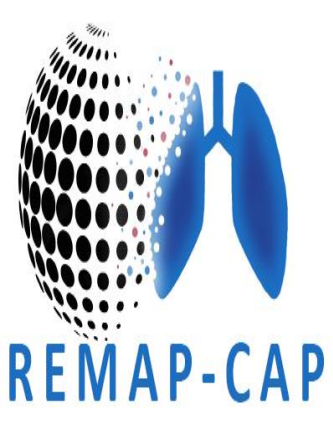
Efficient Trial Design

- Seamless Phase 2/3
- Adaptive platforms

Collaboration

- Existing infrastructure
- Multidisciplinary teams

Fundamentals of good design still apply



- REMAP-CAP
- *A Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia*

<https://doi.org/10.1513/AnnalsATS.202003-192SD>



Engaging Patients and the Public

Firmly embed PPIE in our culture to;

'increase both the value, integrity and quality of the research'

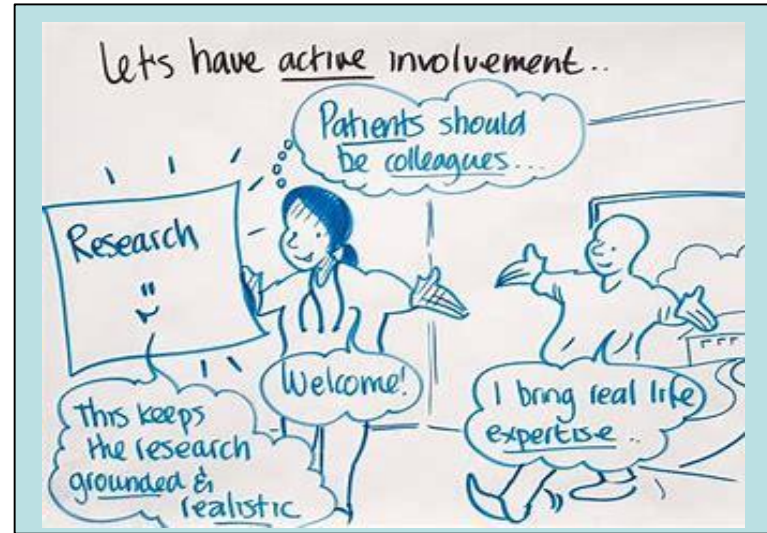
Alice Biggane, Maria Olsen, Paula R Williamson
TMRP Workshop on PPI with Trial Methodology Research.
<http://www.methodologyhubs.mrc.ac.uk/tmrp-what-trial-methodology/>

Educate and empower the public

Meaningful PPIE throughout all of our research

*'too often when we' (PPI contributors)
'do involvement, we are becoming
more like you (researchers), and the
real challenge is – how do you become
more like us'*

Marita Hennessy



Addressing Inequalities

Embed equality, diversity and inclusion

*'Research not suitable for patient
Not
Patient not suitable for research'*

Access to research for all



PRINCIPLE

Platform Randomised trial of INterventions
against COVID-19 In older peoPLE

Conclusions

Covid 19 has demonstrated the strength, resilience and expertise of the UK's health research ecosystem

We must work together to ensure we can learn the lessons from the pandemic response

Methodologists have a key role to play

Together we can maintain our position as a world leader in health research and impact patients lives

Thank you !