



# Trials within Cohorts (TwiCs): review of an innovative approach to practical trials: the 'cohort multiple RCT' design

## Background

The 'cohort multiple randomised controlled trial' (cmRCT) is an innovative approach to the design and conduct of RCTs which compare the effectiveness of interventions to usual care (Relton et al, 2010). The design utilises a large long term observational cohort of people with the condition of interest, regularly measuring the outcomes of the whole cohort. The cohort in the cmRCT design allows multiple trial populations to be quickly identified and recruited and multiple interventions tested against usual care. Information and consent processes aim to be as similar as possible to those in routine healthcare.

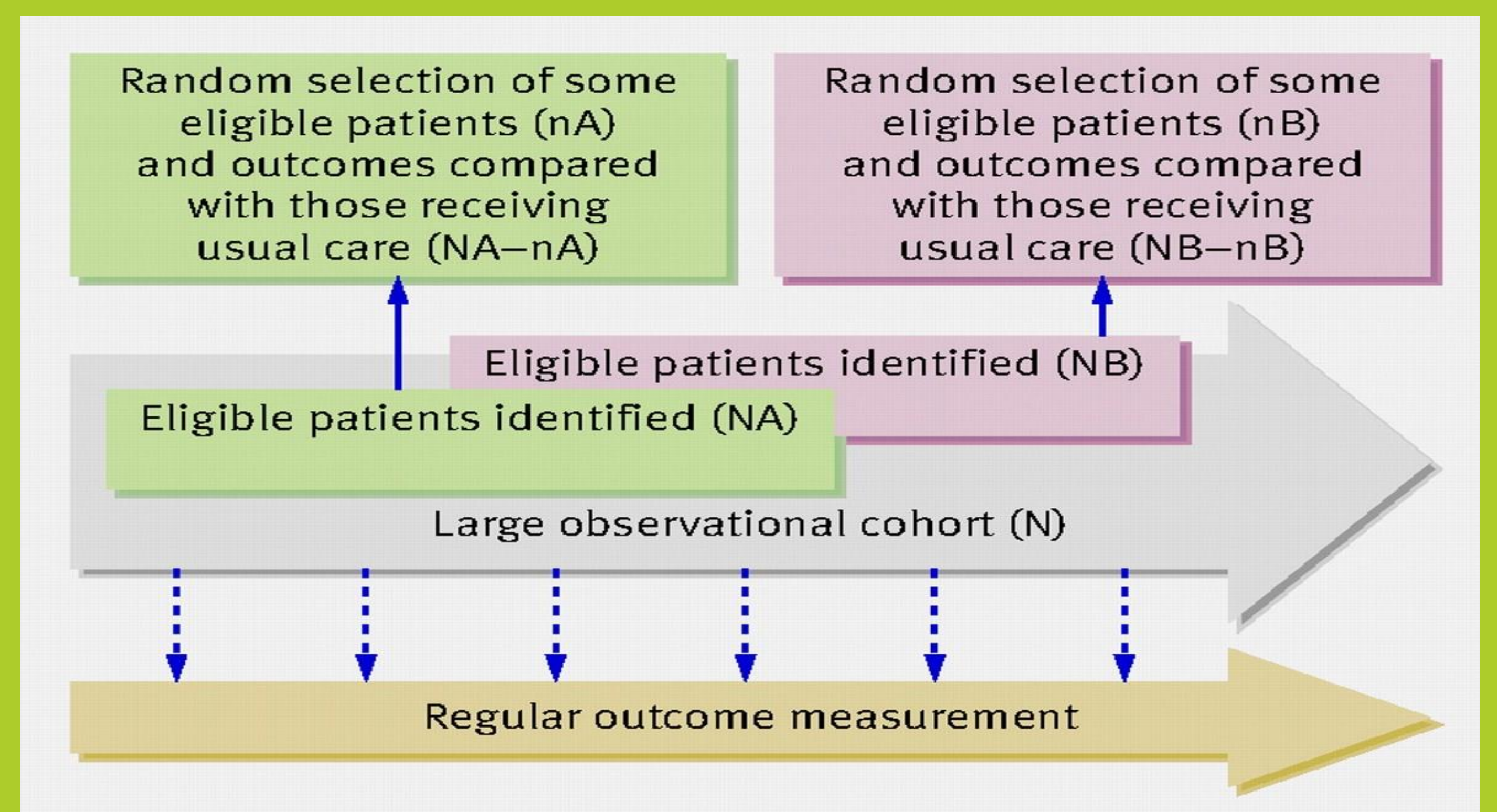
In order to guide researchers interested in using the cmRCT design a review of use of the design was conducted.

## Methods

Studies using the design were identified through citations of the original theoretical article (Relton et al 2010, BMJ, 2010). Data were extracted from published articles, study protocols and presentations.

## Results

18 cohort studies implementing the cmRCT design were identified with a total of 19 ongoing or completed trials embedded within these cohorts. Some cohorts focussed on a single disease or injury (e.g. hip fracture, breast cancer, colorectal cancer, ADHD), others had a wider focus (e.g. risk of mental health conditions, risk of falls). The majority cohort studies were based in UK population or community or primary care settings.



COHORT STUDY NAME	CONDITION / AREA OF INTEREST (Yr recruitment begun)	INTERVENTION(S) BEING TRIALLED (TRIAL name)
<b>Community/ Primary care settings</b>		
<b>UK</b>		
REFORM	At risk of falls (elderly) (2013)	Podiatry intervention (REFORM)
YHS	Long Term Conditions (adults) (2011)	Homeopathy for depression (DEPSY)
CASPER	At risk of depression (65yrs+) (2011)	Screening & psychological treatments, (CASPER, CASPER+ SHARD, CASPER-ISP)
CLASSIC	Long Term Conditions (Older people) (2015)	Health coaching (PROTECTS)
CARE	Frailty (75yrs+) (2015)	(General health, psychosocial and rehabilitation interventions planned)
BIBs	Irritable Bowel Syndrome (2011)	Supportive listening, homeopathy
Hot Flush	Menopausal hot flushes (2007)	Homeopathy
Low Back Pain	Low Back Pain (2012)	Manual therapy, Acupuncture
STAR	ADHD (5-18yrs) (2015)	Nutritional therapy
BiBBS	Families with babies (2016)	Individual and structural public health interventions (pre birth to school)
<b>Canada</b>		
ABCD	Diabetes (2012)	Collaborative care vs screening for depressive symptoms
SPIN	Scleroderma (2012)	(Psychosocial & rehabilitation interventions planned)
FORBOW	At risk of severe mental illness (0-24yrs) (2014)	Cognitive-behavioural therapy-based Skills for Wellness (SWELL) skill training
<b>Hospital settings</b>		
<b>UK</b>		
WHiTE	Hip fracture (60yrs+) (2012)	3 types of fracture treatment (WHiTE one, WHiTE two, WHiTe three Hemi)
<b>Finland &amp; Netherlands</b>		
FIDELITY (Finland)	Degenerative knee injury (2013)	Surgery (APM)
PICNIC	Colorectal Cancer (2014)	Chemo radiation (RECTAL BOOST), Surgery (SPONGE), 7T MRI
UMBRELLA	Breast Cancer (2014)	Compression vest, Exercise program (FIT),
PRESENT	Bone Metastases (2014)	Irradiation (VERTICAL), Irradiation (HIFU)

## Conclusions

This review of the cmRCT design in practice provides examples of the design in hospital and community/ primary care settings, both in the UK and abroad. Future research is needed to assess the acceptability and efficiency of this approach to producing rigorous evidence of practical use, i.e., if/when this design is preferable to the standard approach to single separate RCTs.