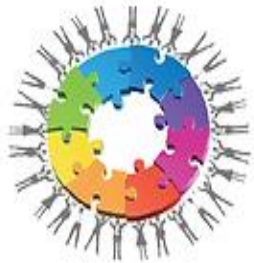


"Staged-and-Tailored" Informed Consent Symposium



Wednesday 13th September 2023

10am-4pm GMT, 11am-5pm CEST, 5am-11am EST

Online



Sharing and exploring what is known about the use, acceptability, and efficiency of staged-and-tailored approaches to informed consent.

Scientific Organising Committee

UK: Dr Julia Wade, Professor Julius Sim, Beverley Nickolls,
Dr Indrani Manoharan, Dr Clare Relton

Switzerland: Dr Alain Amstutz

The Netherlands: Dr Roxanne Gal, Dr Lois Daamen

USA: Dr Andrew Vickers

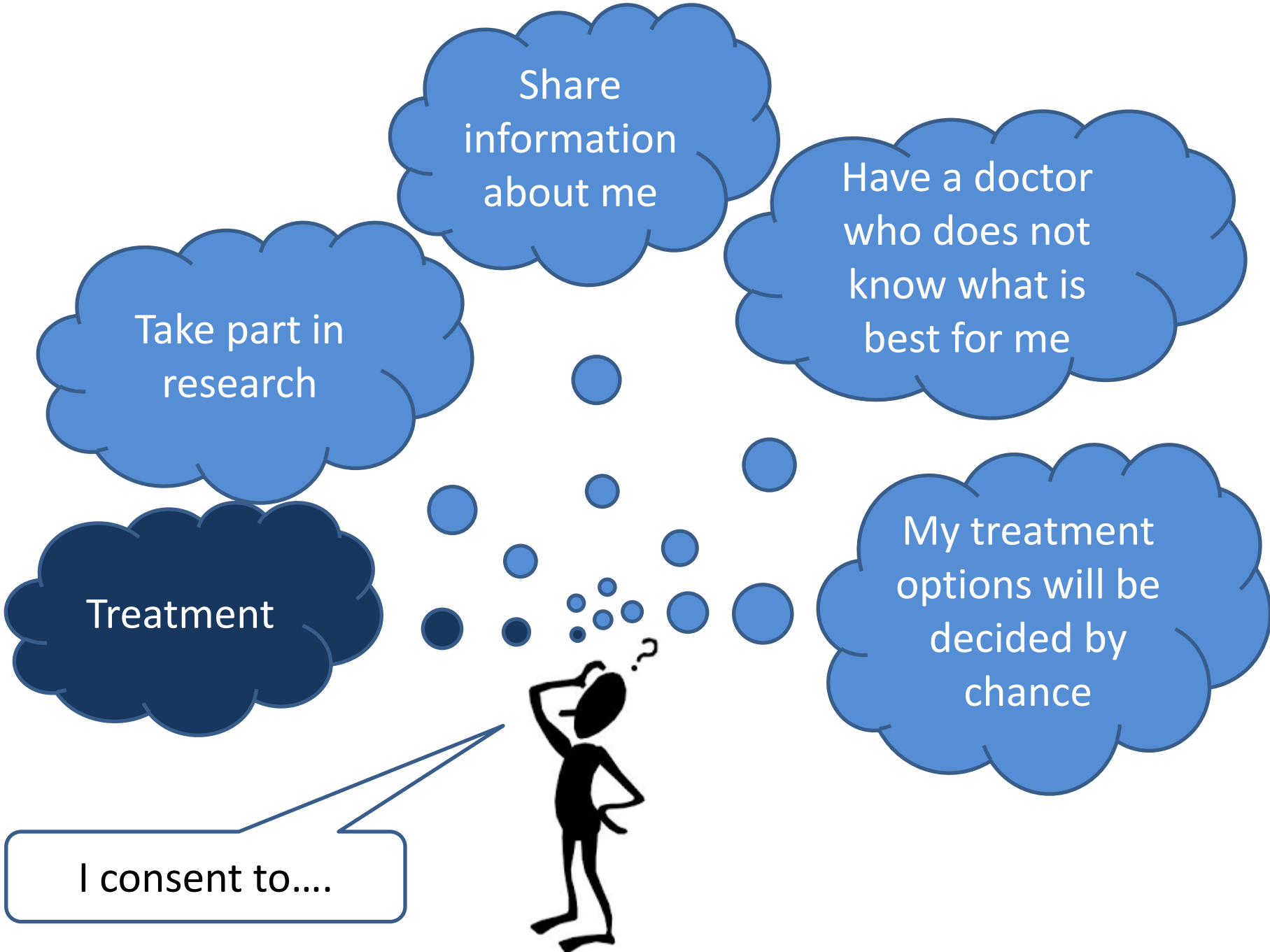
How do we talk to people about taking part in research?

How do we ethically minimize participant (cognitive & emotional) burden and efficiently produce realtime results of use to trial stakeholders?

What are the best approaches to optimise the informed consent process to improve recruitment of members of the public to randomised trials?



Recruitment in Randomised Trials Top Priorities (priority setting in association with the JLA)



Share information about me

Have a doctor who does not know what is best for me

Take part in research

Treatment

My treatment options will be decided by chance

I consent to....

Informed consent



Research purpose & steps involved
Process of randomisation
Risks & benefits of taking part
Right to withdraw at any time



- ✓ Freely given
- ✓ Specific
- ✓ Informed
- ✓ Unambiguous

Confusion

Influence of context often ignored

Improving IC processes

Content of information
(length, readability....)

Mode of delivery
(paper, multimedia etc)

CONSORT Guidelines
*“Describe whether and how
consent was obtained”*

CONSORT ROUTINE: Kwakkenbos 2021

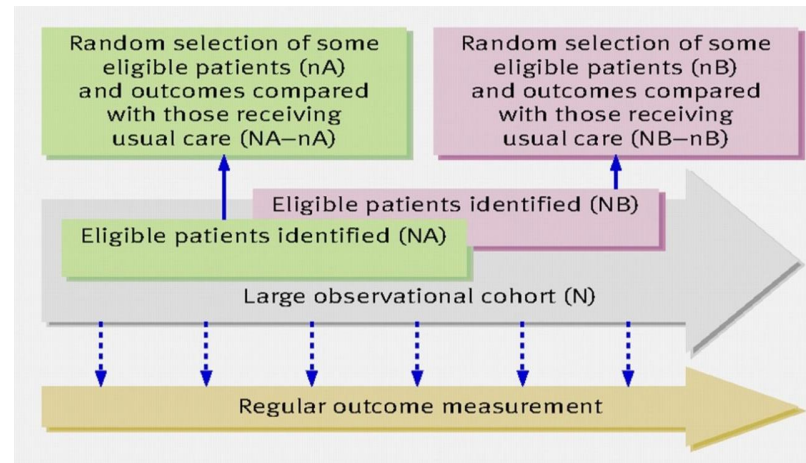
Core Outcome Sets for
evaluating interventions to
improve IC in clinical trials

ELICIT Study; Gillies et al 2021

Innovative Trial Designs

- TwiCs/ Cohort Multiple RCT - Patient-centred IC (Relton 2010)
- Staged-informed Consent in the Cohort Multiple RCT Design (Young-Afat 2016)
- Staged & Tailored IC approach (Nickolls & Relton)

Trials within Cohorts (TwICs)



Cohort (new or existing) provide observational data from outset

For each trial

Intervention group



"You have been randomly selected intervention"

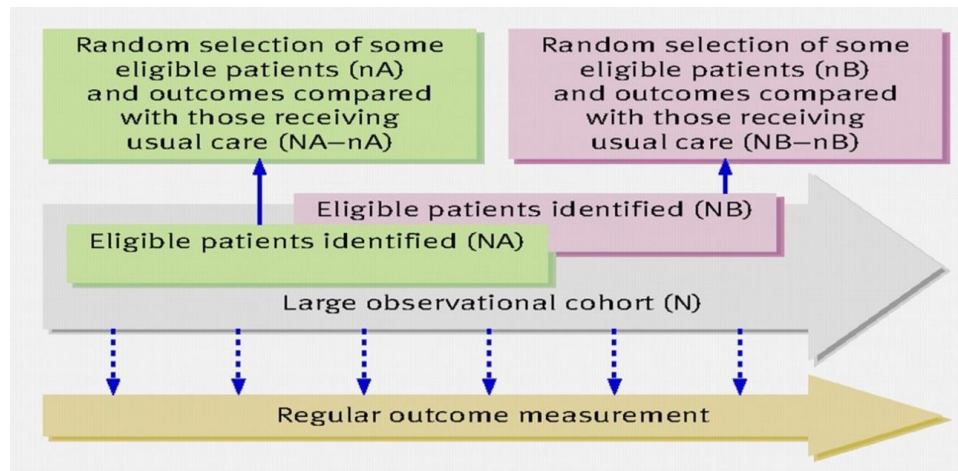
Control (usual care) group

No recontact

TwICs

“Patient centred IC”

“Replicate procedures that exist in routine health care, where patients receive information they need, at the time they need it.”





Staged & Tailored Approach

Tailoring informed consent process to the needs of each group/patient at each stage

“chunking it down”

Observing vs experimenting



Unavailable treatments



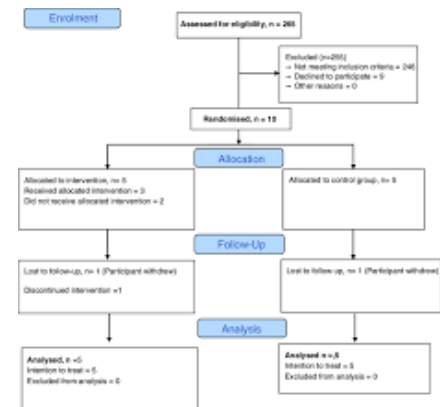
randomisation
staged and tailored

Discussing IC

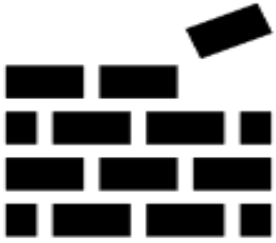
- Terminology
- Trial reports/ flow diagrams – lack detail

Pragmatic vs explanatory trials,
Cohort multiple RCT design, Cohort
embedded RCT design, Trials within
Cohorts (TwiCs), Staged consent
RCT design, Randomised consent
design, Zelen design (single and
double), Platform trials,
Randomised registry trials,
Comprehensive cohort trials,
Standard of care (SOC), Treatment
as usual (TAU).....

Fully informed consent
Patient-centred consent
Tailored disclosure
Proportionate consent
Randomisation without consent
Broad consent
Pre randomisation broad consent
Just in time consent
Two stage consent
Delayed consent
Tiered-layered staged consent.....



- Difficult to discuss

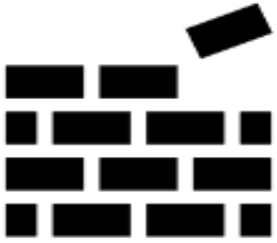


The Informed Consent Decisions & Choices (ICDC) Tool

- Mapping decisions and choices for participants and trial designers at every stage

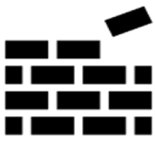
Relton & Amstutz

Who gives Information	What
HCP	RQ & rationale
HC organisation - GP practice, hospital	Data collection/ use of data
Research organisation	Random selection to group
Trained non-HCP	Intervention
Government	Control (no exp intervention)
Media	Tests, Blood samples etc
Who gives Consent	How
Patient	F2F
Member of the public	Verbal
Research participant	Written
Group e.g. cluster guardian	Electronic: Written + signature/ thumbprint
Proxy - parent, carer	Phone
	Video
When	Where
Entry into system/ institution	Clinical setting
At risk of disease	Emergency treatment
Disease onset/ diagnosis	Non healthcare setting
Treatment onset	Other
Treatment failure	
Before randomisation	
After randomisation	
Before baseline data collection	
After baseline data collection	



EXAMPLE

Standard approach to informed consent



One single stage

STANDARD APPROACH

WHAT

1. Contact by research team

2. Use of routinely collected and/or observational data

3. Provide additional data

4. Additional tests

5. Receive experimental treatment

6. Random allocation

WHEN

Before

Before

Before

baseline data collection

random allocation

experimental tx delivery

WHO

Target population

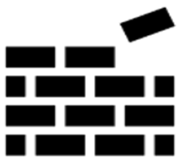




EXAMPLE



Staged & tailored approach to informed consent
- Hospital setting



STAGE 1 of 2

WHAT

1. Contact

2. Use of routinely collected and/or observational data

3. Provide additional data

6. Future randomisation

7. SOC w/o further notice (control group only)

WHEN

Before

baseline data collection

Before

random allocation

Before

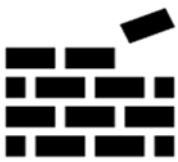
experimental treatment delivery

WHO (Tailored)

Pancreatic cancer patients at Dutch cancer centres

Cohort: [The Dutch Pancreatic Cancer Project \(PACAP\)](#)





STAGE 2 of 2

WHAT

1. Contact

2. Use of routinely collected and/or observational data

3. Provide additional data

5. Receive experimental treatment

6. Future randomisation

7. SOC w/o further notice (control group only)

WHEN

Before

After

baseline data collection

Before

After

random allocation

Before

experimental treatment delivery

WHO (Tailored)

Pancreatic cancer patients at Dutch cancer centres

Already consented to 1

Already consented to 2

Already consented to 3

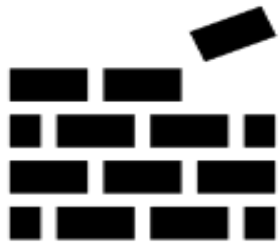
Already consented to 6

Already consented to 7

Cohort: [The Dutch Pancreatic Cancer Project \(PACAP\)](#)

RCT: [Recurrent Disease Detection After Resection of Pancreatic Adenocarcinoma Using a Standardized Surveillance Strategy](#)





EXAMPLE



Staged & tailored approach to informed consent
- Community setting



STAGE 1 of 3

WHAT

1. Contact

2. Use of routinely collected and/or observational data

8. Other: information *'to look at the benefit of health treatments'*

WHEN

Before

baseline data collection

Before

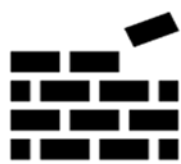
random allocation

Before

experimental treatment delivery

WHO (Tailored)

General/HC system members



STAGE 2 of 3

WHAT

1. Contact

2. Use of routinely collected and/or observational data

8. Other: information 'to look at the benefit of health treatments'

WHEN

Before

baseline data collection

Before

random allocation

Before

experimental treatment delivery

WHO (Tailored)

General/HC system members

People with depression/anxiety

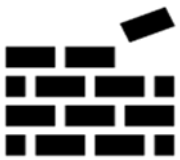
Already consented to 1

Already consented to 2

Cohort recruitment: [South Yorkshire Cohort \(Yorkshire Health Study\)](#)

Sub-Cohort recruitment: [South Yorkshire Cohort \(Yorkshire Health Study\)](#)





STAGE 3 of 3

WHAT

1. Contact

2. Use of routinely collected and/or observational data

5. Receive experimental tx

8. Other: information 'to look at the benefit of health treatments'

Cohort recruitment: [South Yorkshire Cohort \(Yorkshire Health Study\)](#)

Sub-Cohort recruitment: [South Yorkshire Cohort \(Yorkshire Health Study\)](#)

RCT: [DEPSY 1st RCT within the South Yorkshire Health Study Cohort](#)

WHEN

Before

After

baseline data collection

Before

After

random allocation

Before

experimental tx delivery (intervention)

WHO (Tailored)

General/HC system members

People with depression/anxiety

Already consented to 1

Already consented to 2

Already consented to 8



1000	Overview and Introduction to Staged & Tailored Informed Consent (Relton)
REAL WORLD EXAMPLES	
1015	A. Reviews of published studies
1035	B. Hospital settings
1035	KEYNOTE TALK - <i>Netherlands (Lenny Verkooijen)</i>
1145	C. Community & criminal justice settings
1235	L U N C H B R E A K (30 mins)
1305	USA - example
1315	Breakout session I - <i>What did we learn? What questions do we have?</i>
1335	THINKING
1335	KEYNOTE TALKS - <i>USA & UK (Scott Kim & Julius Sim)</i>
1500	Breakout session II - <i>What did we learn? What questions do we have?</i>
1515	PANEL DISCUSSION
1600	Close