Online randomised controlled trials: What can they tell us

Helen Christensen

Centre for Mental Health Research

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Karolinska Institutet, Stockholm, Sweden

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Aims of Presentation

Describe online randomised controlled trial to determine How much is enough? (MoodGYM mark II).

Describe the issues raised by them

Describe the design of new series of online randomised controlled trials
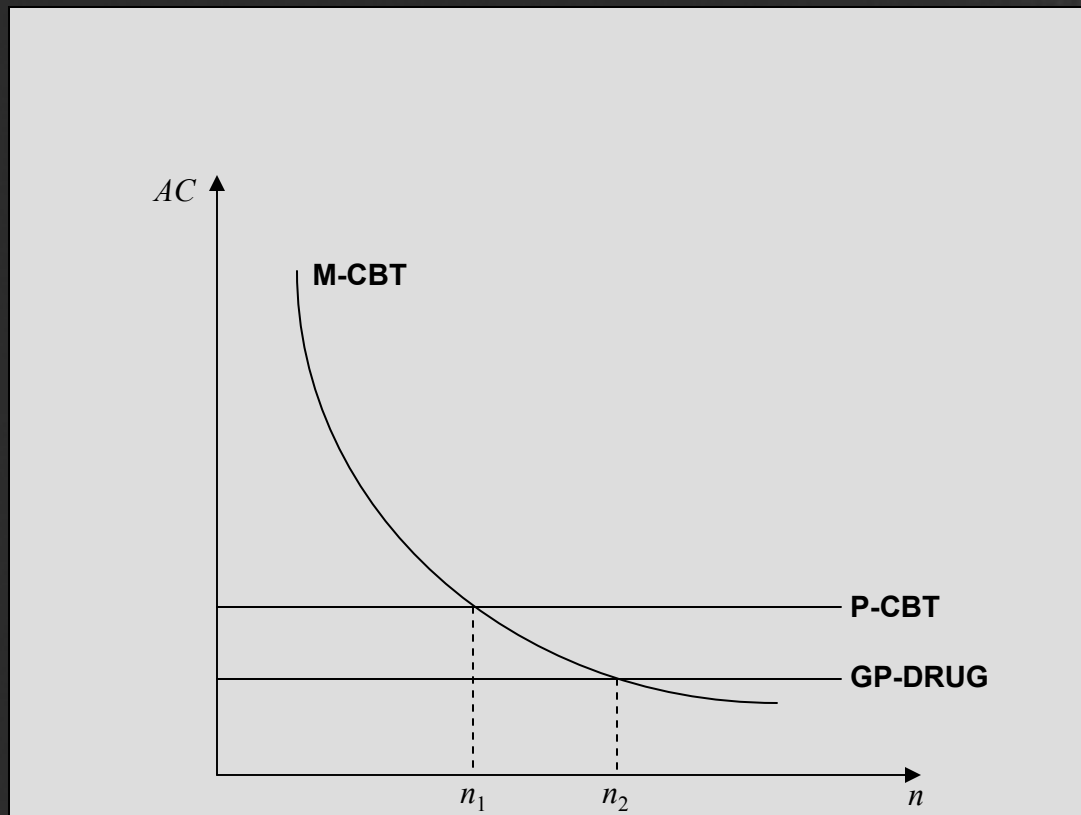
Describe new directions

Evidence to date

Interventions are effective

Interventions are cost effective

It is cost effective

Butler, Bartlett, Christensen and Groves (in preparation)

High development costs but diminishing costs as the number of users increases

Software attached to evaluate interventions

There is now recognition of the power of the internet to improve communication and to co-ordinate large scale randomised controlled trials. In particular, the internet is used to

Improve communication

Centralize and secure data

Distribute information

Table 1: Cumulative number of randomized control trials (RCTs) versus online RCTs (based on Medline and Old Medline searches from 1950) on a logarithmic scale over time.
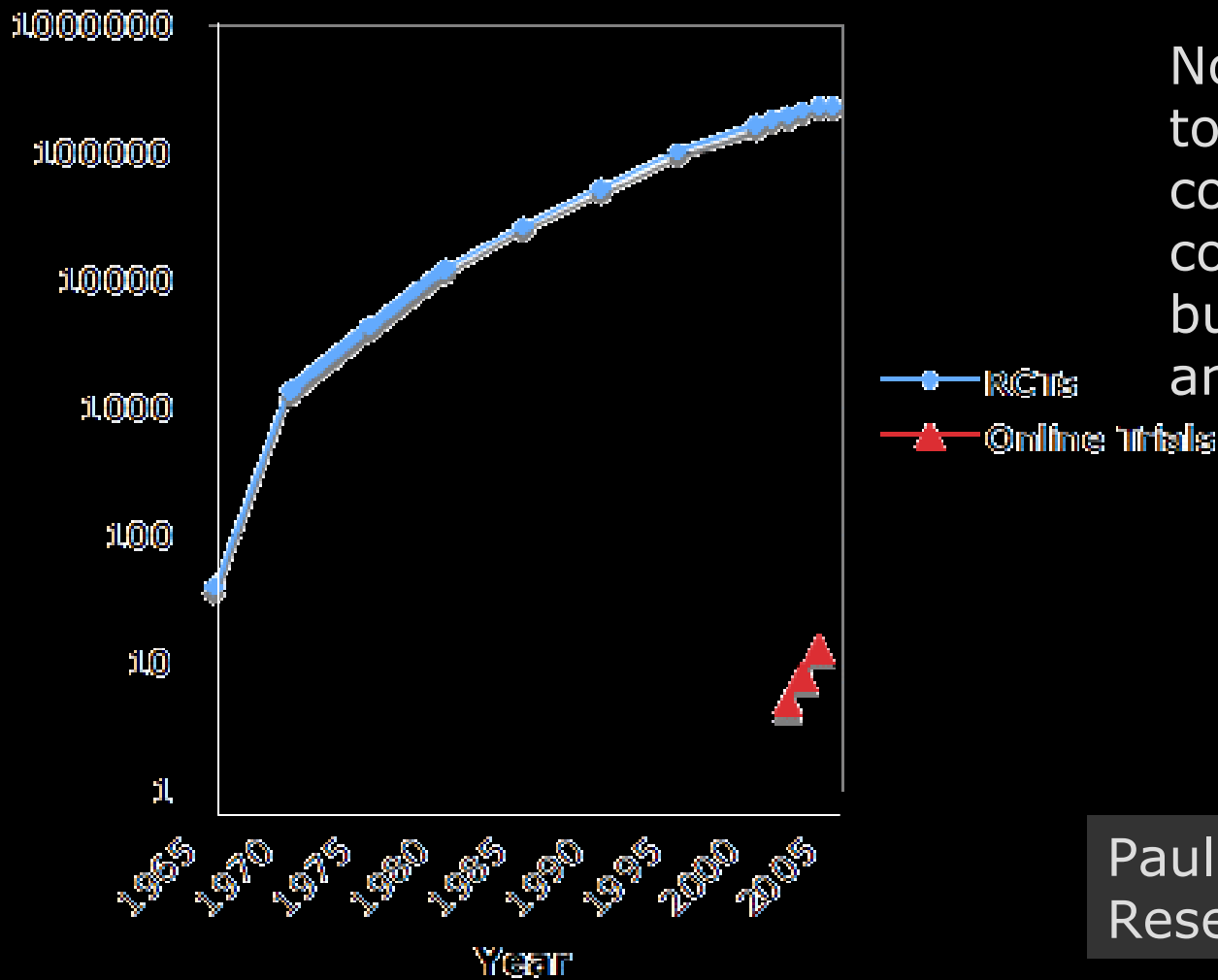
Note: RCTs refer here to the use of online coordination and data collection of the trials but not to the use of an online intervention

RCTs

Online Trials

Year

1000000
100000
10000
1000
100
10
1

Paul, Seib and Resecott, 2005

MoodGYM: online intervention with online trial infrastructure

MoodGYM combines all Internet features of online randomised controlled trial but also includes an online intervention

Hence, MoodGYM can deliver fully automatised randomised controlled trials: including recruitment, registration, consent, randomisation, data collection, and data download as SPSS format.

the **MoodGYM**
training program

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Module 1:
WHY YOU FEEL THE WAY YOU DO

:ENTER:

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Module 2:
CHANGING THE WAY WE THINK

:ENTER:

Internet

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qualifying the positive

Dismissing or ignoring any positive comment/ achievement/ compliment.

mping to nclusions

You think negatively about something without supporting evidence. There are two errors:

Mind reading: You think without any evidence that someone is thinking negatively about you

The fortune teller error:
You truly believe that you know what will happen in the future, without evidence.

gnification or imization

This is making small things much larger than they deserve, and making others things much smaller than they are in reality.

otional Reasoning

Thinking that emotional states legitimately reflect reality.

uld Statements

Thinking in terms of **should, must, ought** imposes a view about the way the world is which

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rgeneralization	One example is of a mistake or error is interpreted as a pattern of mistakes, and errors.
ntal Filter	One (negative) part of the picture is examined to the exclusion of the larger (positive) part.
qualifying the itive	Dismissing or ignoring any positive comment/ achievement/ compliment.

nping to nclusions

You think negatively about something without supporting evidence. There are two errors:

Mind reading: You think without any evidence that someone is thinking negatively about you

The fortune teller error:
You truly believe that you know what will happen in the future, without evidence.

What chance do I have of getting that job, I know they will hate me straight away (Mind reading).

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WARPY THOUGHTS TEST
(MoodGYM recommends you complete this quiz at least once as it is an essential part of your workbook)

WARPY THOUGHTS TEST

(Click on the number corresponding to your feelings about each statement)

1 strongly agree
2 agree
3 neither agree or dissagree
4 disagree
5 strongly disagree

The need for aproval from others.

If people criticise me, I am not a worthwhile person.   1 ● 2 ○ 3 ○ 4 ○ 5 ○

Other people's approval is very important to me.   1 ○ 2 ● 3 ○ 4 ○ 5 ○

I can make everyone like me if I just try hard enough.   1 ○ 2 ● 3 ○ 4 ○ 5 ○

The most important thing in the world to me is to be accepted by other people.   1 ○ 2 ● 3 ○ 4 ○ 5 ○

I find it impossible to go against other people's wishes.   1 ○ 2 ● 3 ○ 4 ○ 5 ○

Unless I get consistant praise I feel that I am not worthwhile.   1 ○ 2 ● 3 ○ 4 ○ 5 ○

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Moodgym application on server with a database server and firewall.

Firewall

internet

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database

CMHR Admin interface
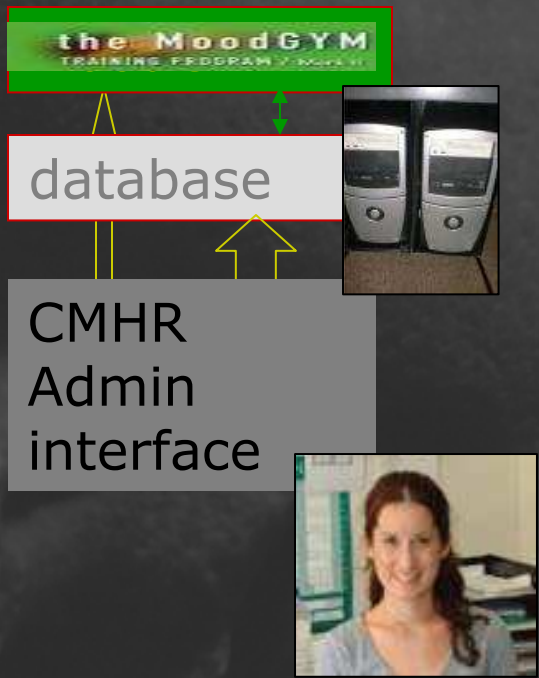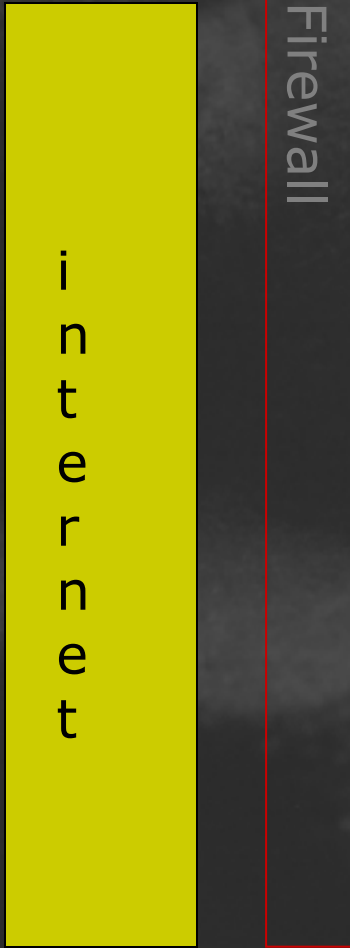
Administrator updates webpages, downloads user data and sets up new trials

Community trials

Firewall

Users Com'ity trial

Users Com'ity trial

Users Com'ity trial

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TRAINING PROGRAM / Mark II

database

CMHR Admin interface

Users find the web site and log on and join trial

Full functionality with four trials running simultaneously and administrators provided with access to research data

Firewall

Users Com'ity trial

Users Com'ity trial

Users Com'ity trial

Users GP

Users Schools

Users Users Tromso
Users Otago, NZ
Users Canada

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TRAINING PROGRAM

database

CMHR
Admin
interface

Trial manager Sydney

Trial manager Canberra

Trial manager Tromso
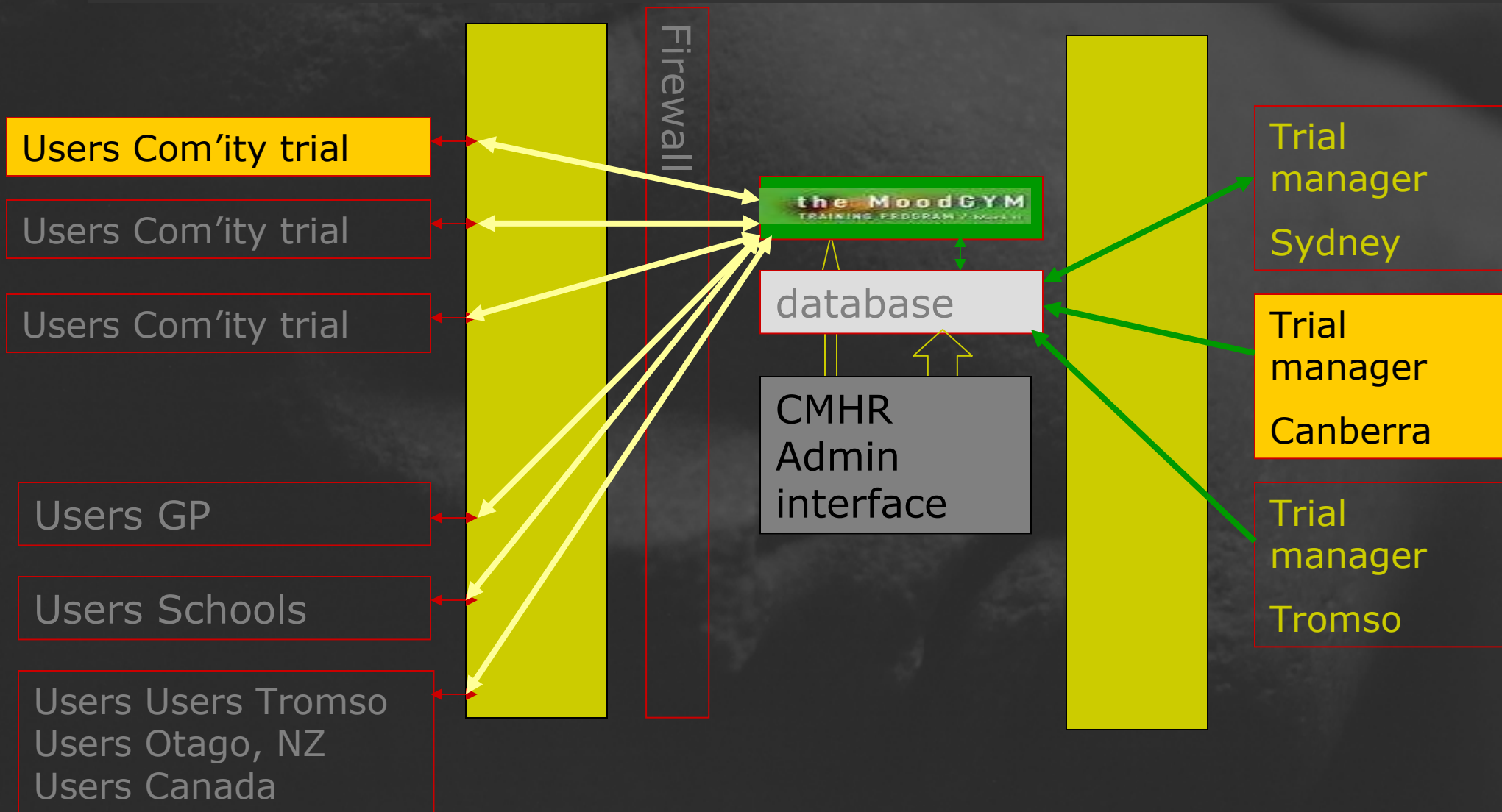
Internet CBT: How much is enough?

6 conditions were examined

These were configurations containing

Brief CBT

Extended CBT

Behavioural Strategies
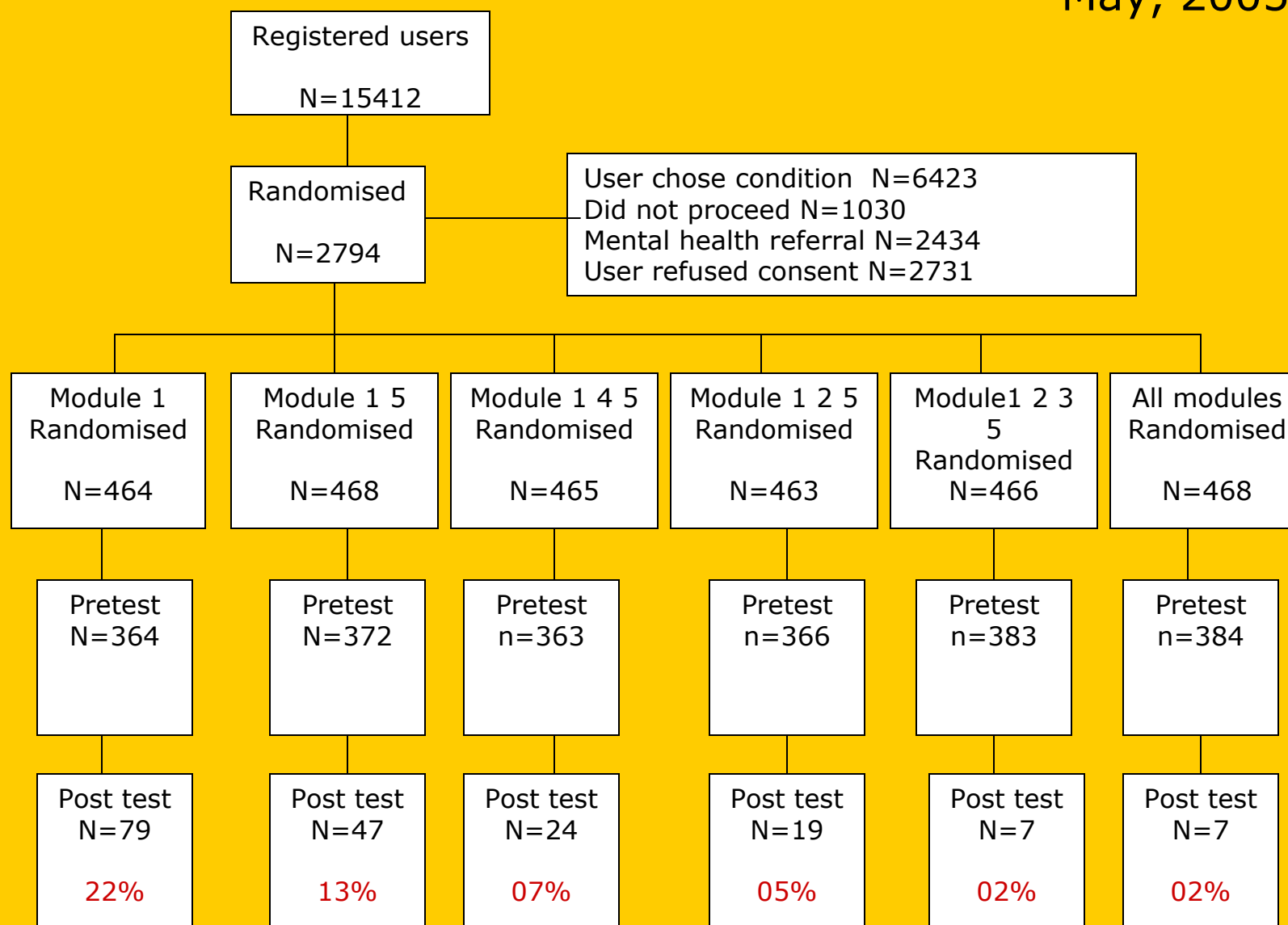
Relaxation

Problem solving

Condition type 1-6

Module 1-5 (sequential)

	Module 1	Module 2	Module 3	Module 4	Module 5
Cond 1	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 2	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 3	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 4	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 5	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 6	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving

Characteristics of randomised groups at pre-test

Intervention	Pretest*	% F*
Module1	6.07	66
Module 1, 5	6.17	66
Module 1,4, 5	6.20	66
Module 1,2, 5	6.31	66
Module 12,3 5	6.00	66
All modules	6.00	66

* ns

Age distribution across conditions
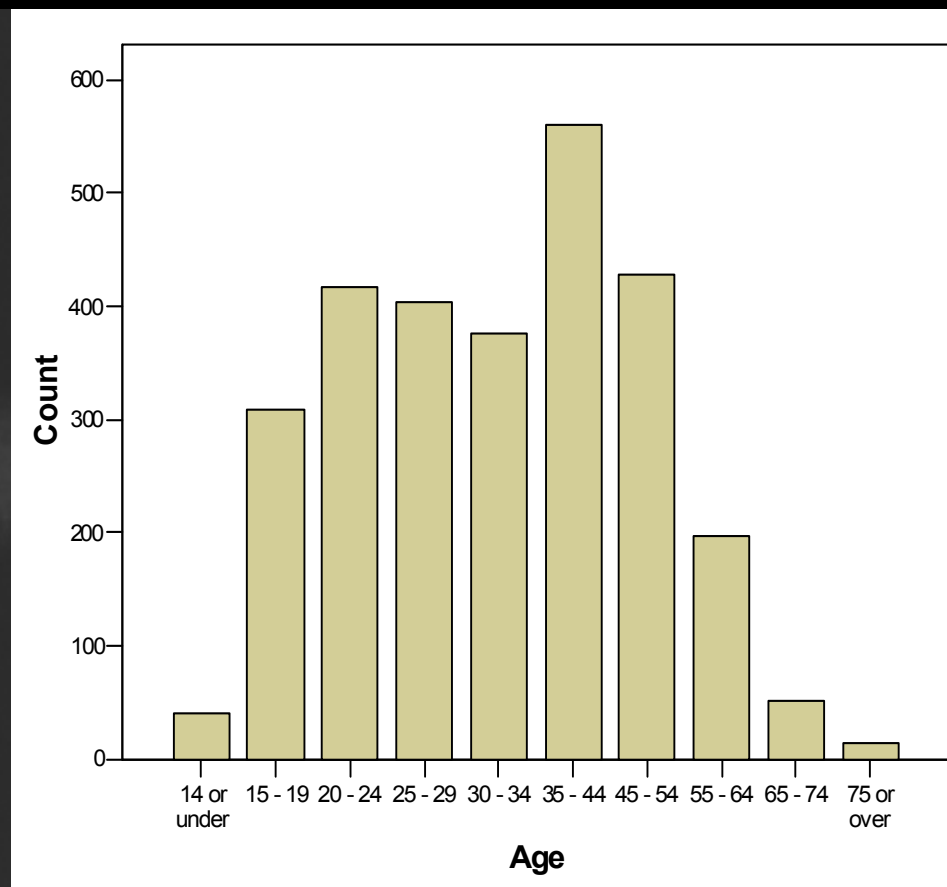
Number of exercises completed

Intervention	N exercises*	range
Module1	2.02	6
Module 1, 5	2.14	6
Module 1,4, 5	2.56	12
Module 1,2, 5	2.60	12
Module 12,3 5	2.65	20
All modules	2.65	25

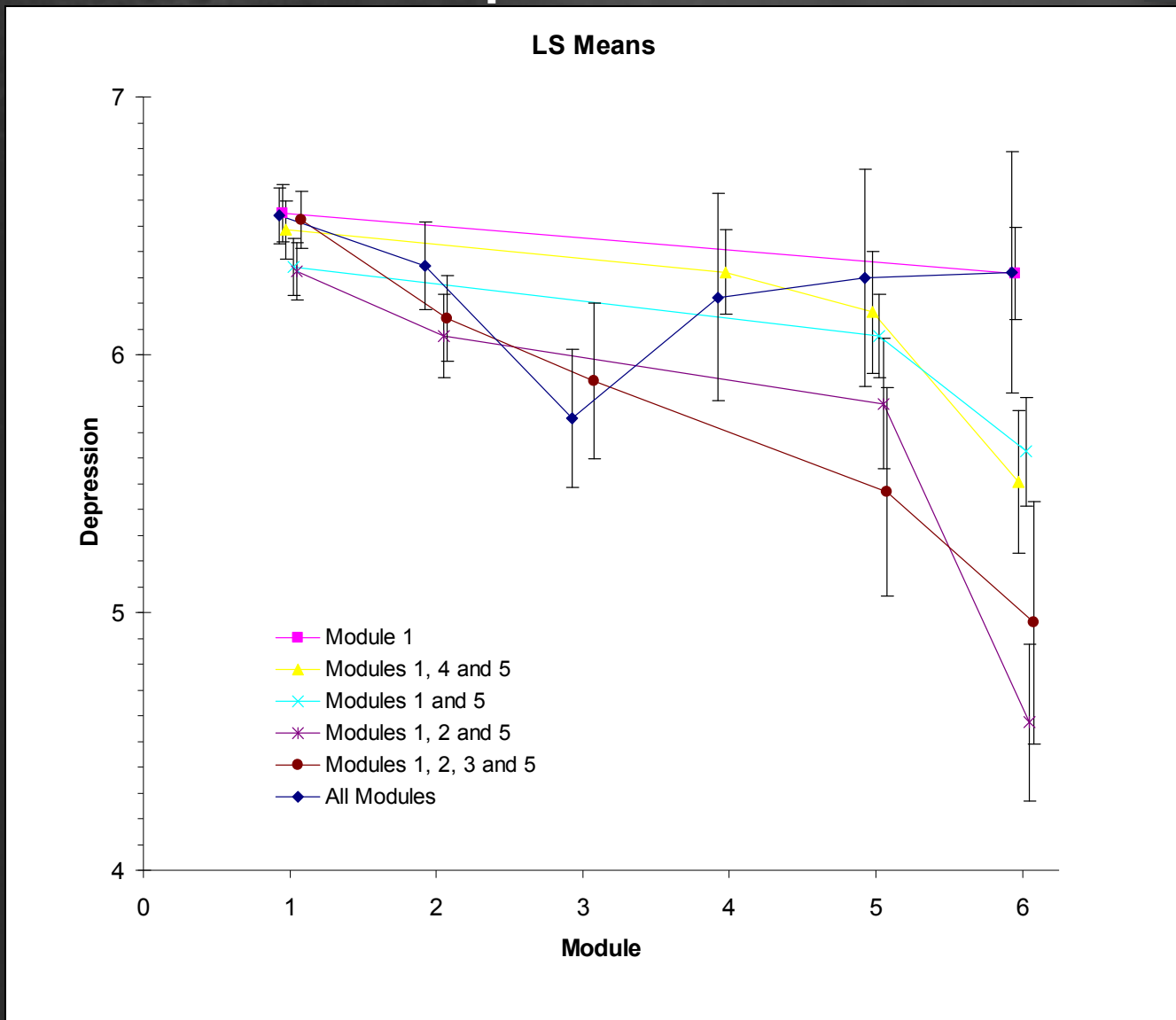Max number =29, n=2793

Analysis

Analysis was undertaken using SAS Proc Mixed (9.1) which can handle planned missingness (due to the non-administration of particular modules in some conditions).
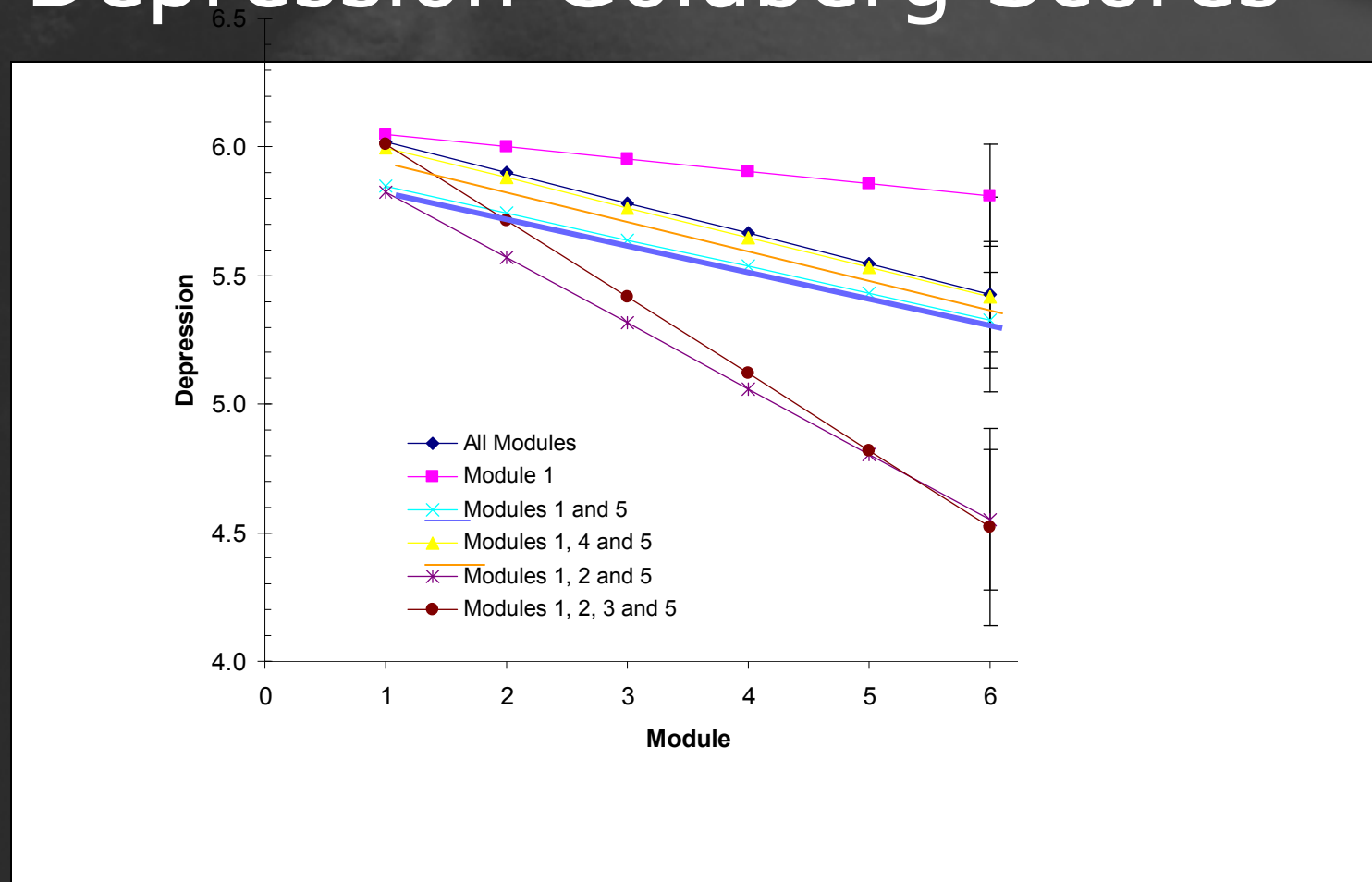
Depression

LS Means

Least Squares means for Goldberg Depression Scale as a function of Module completed. Treatment by Time is statistically significant

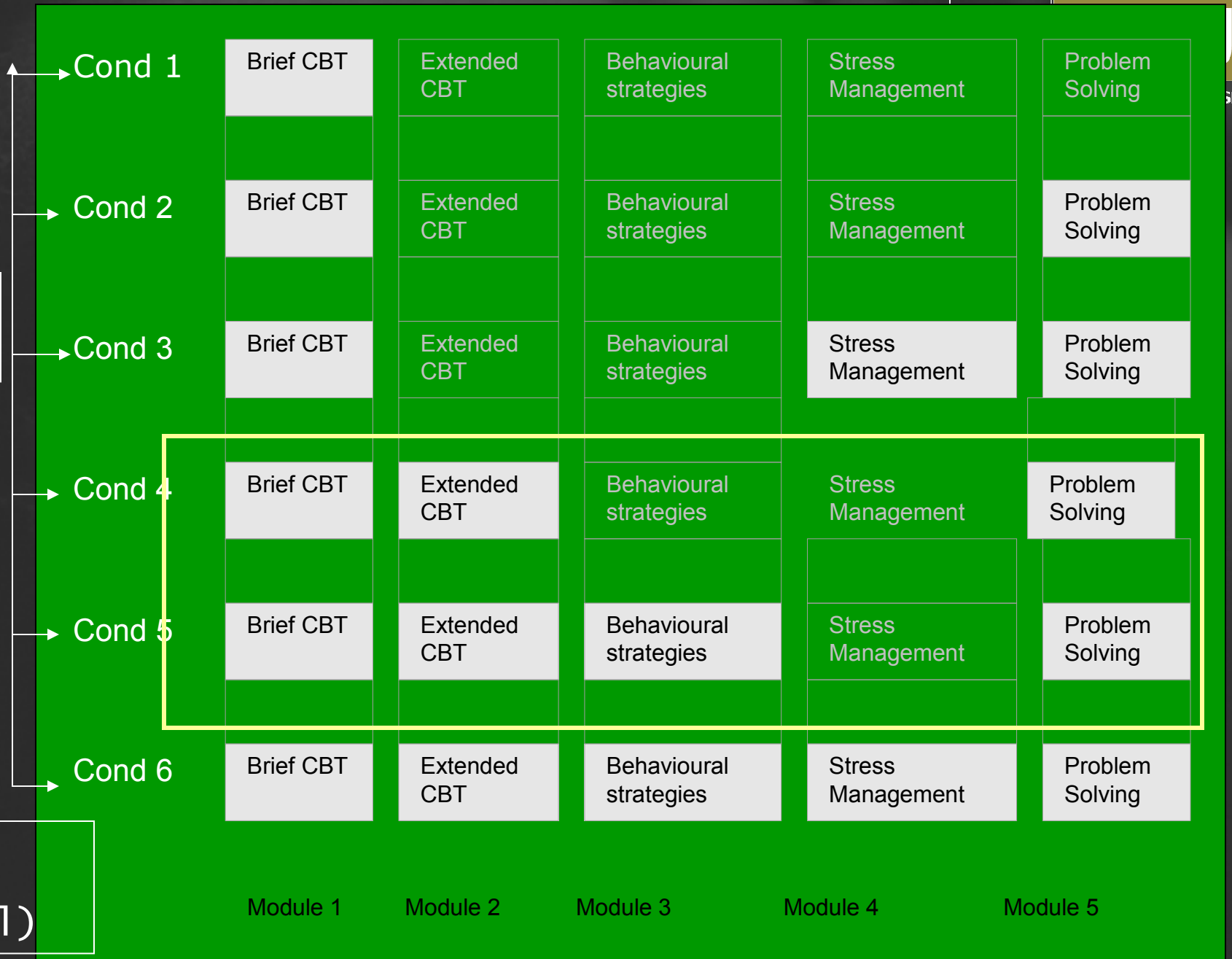# Depression Goldberg Scores

Linear summary

Change on dysfunctional thinking

Time x intervention type is significant

Intervention	Pretest	Posttest n
Module1	3.19	3.13 (43)
Module 1, 5	3.03	2.91 (38)
Module 1,4, 5	3.08	2.94 (23)
Module 1,2, 5	3.24	2.97 (17)
Module 12,3, 5	3.40	2.80 (6)
All modules	3.31	2.92 (7)

Repeated measures design

Condition Type 1-6

Module 1-5 (sequential)

	Module 1	Module 2	Module 3	Module 4	Module 5
Cond 1	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 2	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 3	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 4	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 5	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving
Cond 6	Brief CBT	Extended CBT	Behavioural strategies	Stress Management	Problem Solving

How much is enough?

- Depression and dysfunctional thinking improve
- A single module of brief CBT is not effective relative to other versions in reducing depression symptoms.
- Extended CBT with or without behaviour strategies results in greatest reduction of depression symptoms
- The stress reduction modules do not add

What issues do they identify?

A high rate of attrition, which results in difficulties relative to conventional RCT trials in measuring and assessing outcomes. New methodologies are required and new interpretations of retention are needed.

Use of sites is not linear, but trial RCTs are: this identifies a tension between measuring over time and offering an open design 'flat' access site to consumers.

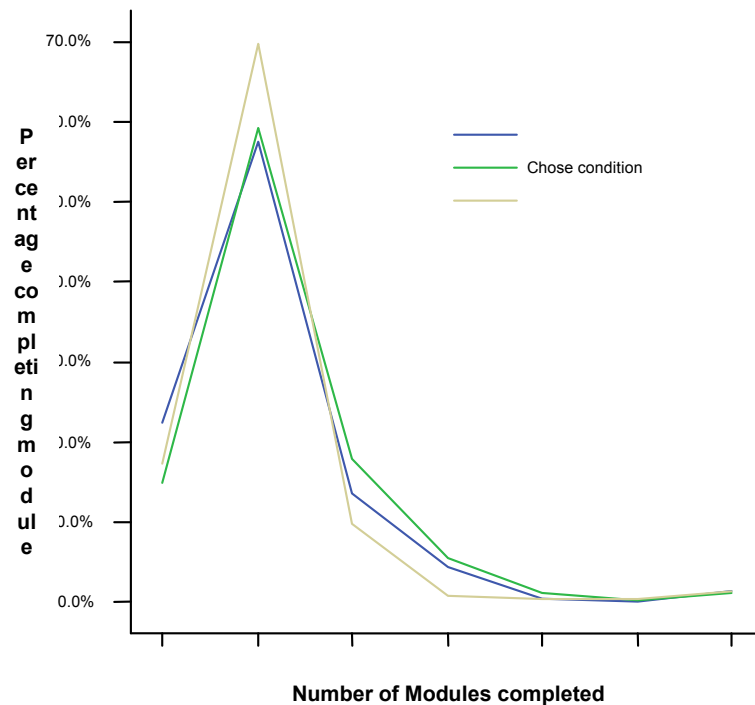New methods and procedures are needed for gaining consent, taking note of preferences.

Attrition
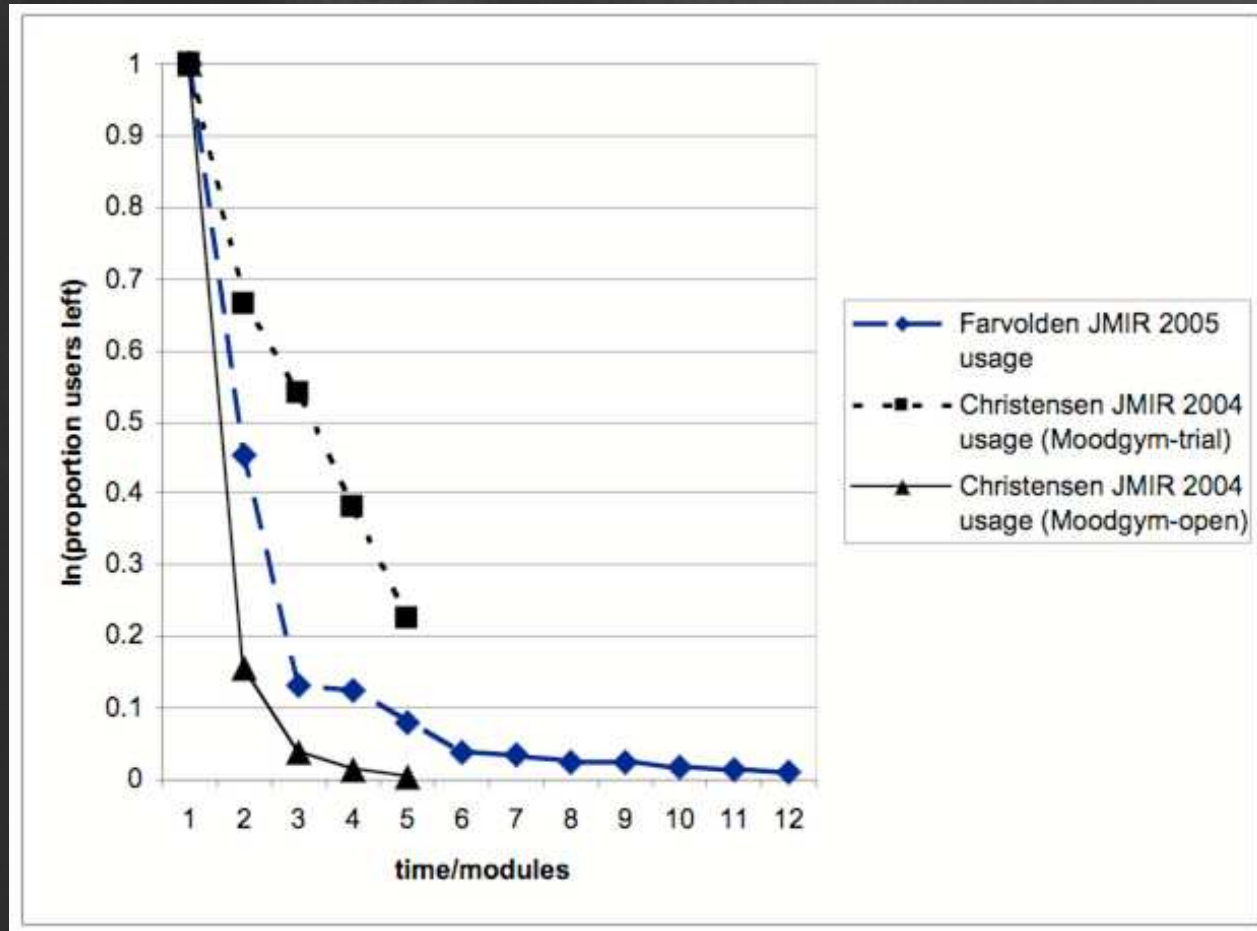
Eysenbach,G. 2005 The Law of Attrition, JMIR, 7 (1):e5,

Preference/condition

Blue: Clinician recommendation

Green: Choose to do full program

Yellow: Randomised
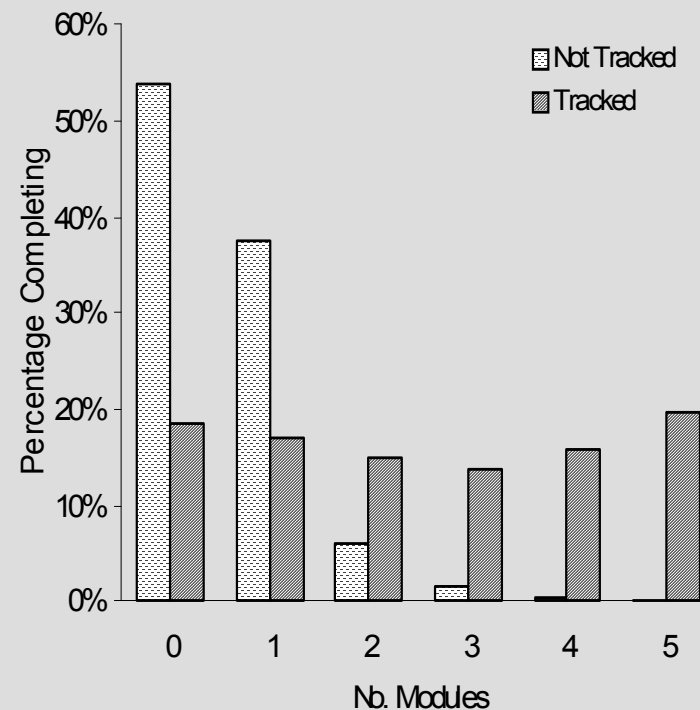
Tracking vs no tracking

Figure 2 Number of modules completed by those not tracked (left) compared to those tracked (right). The number of models completed is higher in those who were tracked.

What can they tell us?

The provide information about the users of internet sites. Levels of symptoms and preferences.

These trials provide information about effectiveness – I.e. the outcomes of the trial in the real world.

They can tell us how to maximize our interventions for best effect: experimentation that wouldn't be funded by itself or is difficult to fund can be done 'effortlessly'.

What can't they tell us?
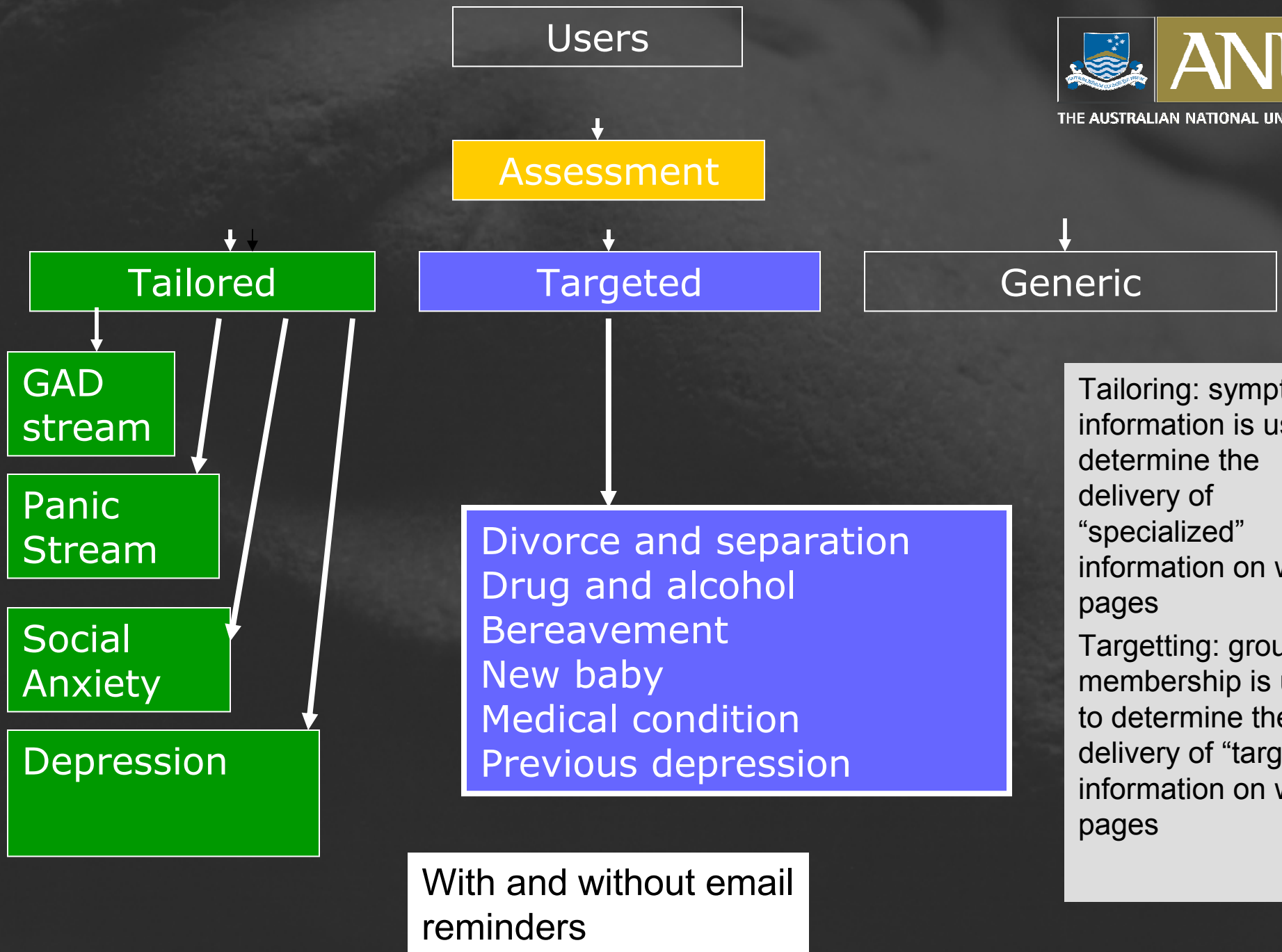
Whether our sites are better than placebo.

- ethical issues about open access websites

How they go compared to non-internet interventions

Whether differences arise from duration to test or length/quality of interventions– shorter interventions are assessed with less delay than longer interventions.

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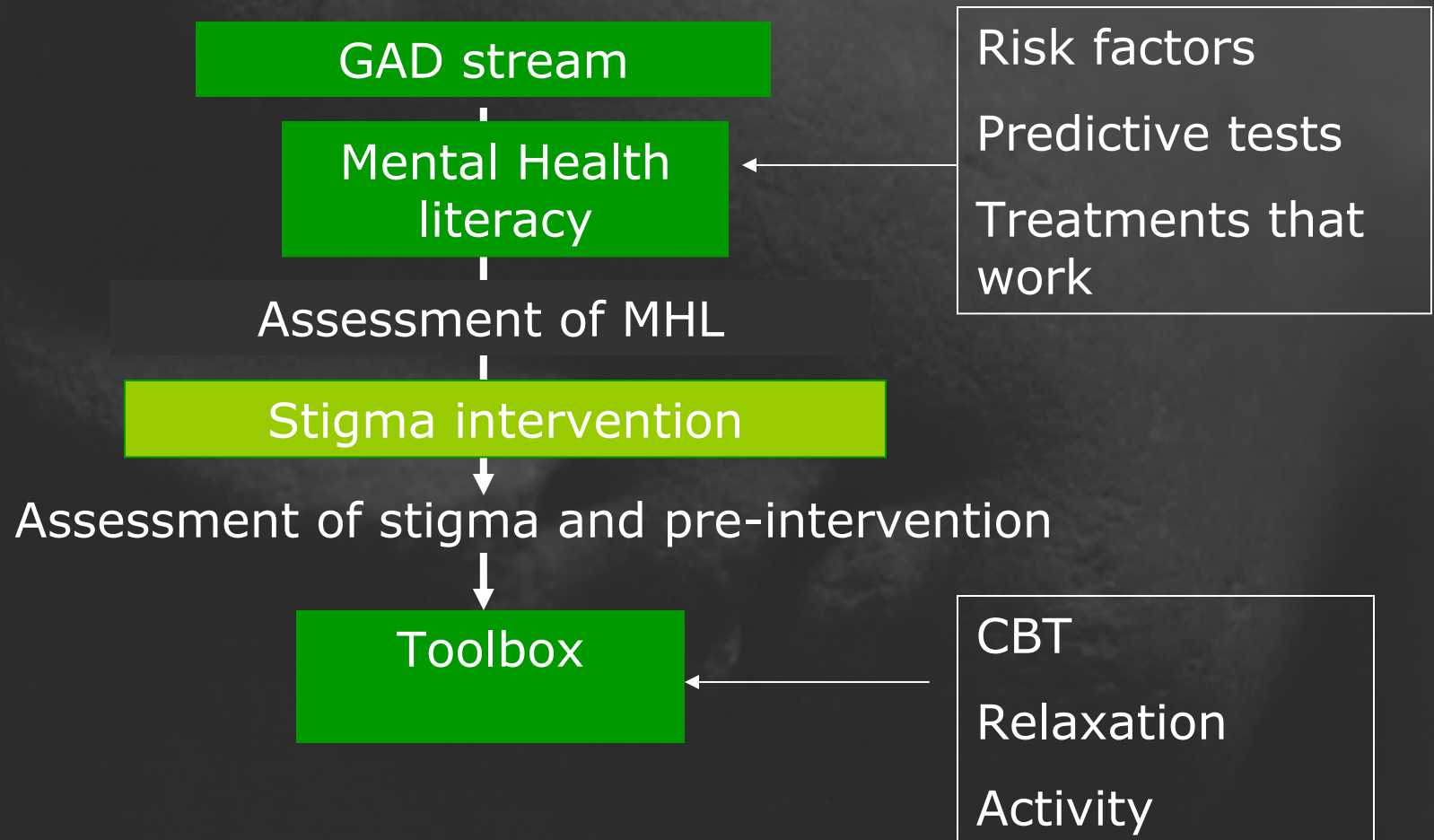
Our next range of internet applications

E-couch aims to test ways to maximize outcomes and to increase help seeking.

Users

↓

Assessment

↓   ↓   ↓

Tailored	Targeted	Generic

Tailored

GAD stream

Panic Stream

Social Anxiety

Depression

Targeted

Divorce and separation
Drug and alcohol
Bereavement
New baby
Medical condition
Previous depression

With and without email reminders

Tailoring: symptom information is used determine the delivery of "specialized" information on web pages

Targetting: group membership is used to determine the delivery of "targetted information on web pages

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Generalized Anxiety Stream

GAD stream

Mental Health literacy

Assessment of MHL

Stigma intervention

Assessment of stigma and pre-intervention

Toolbox

Risk factors

Predictive tests

Treatments that work
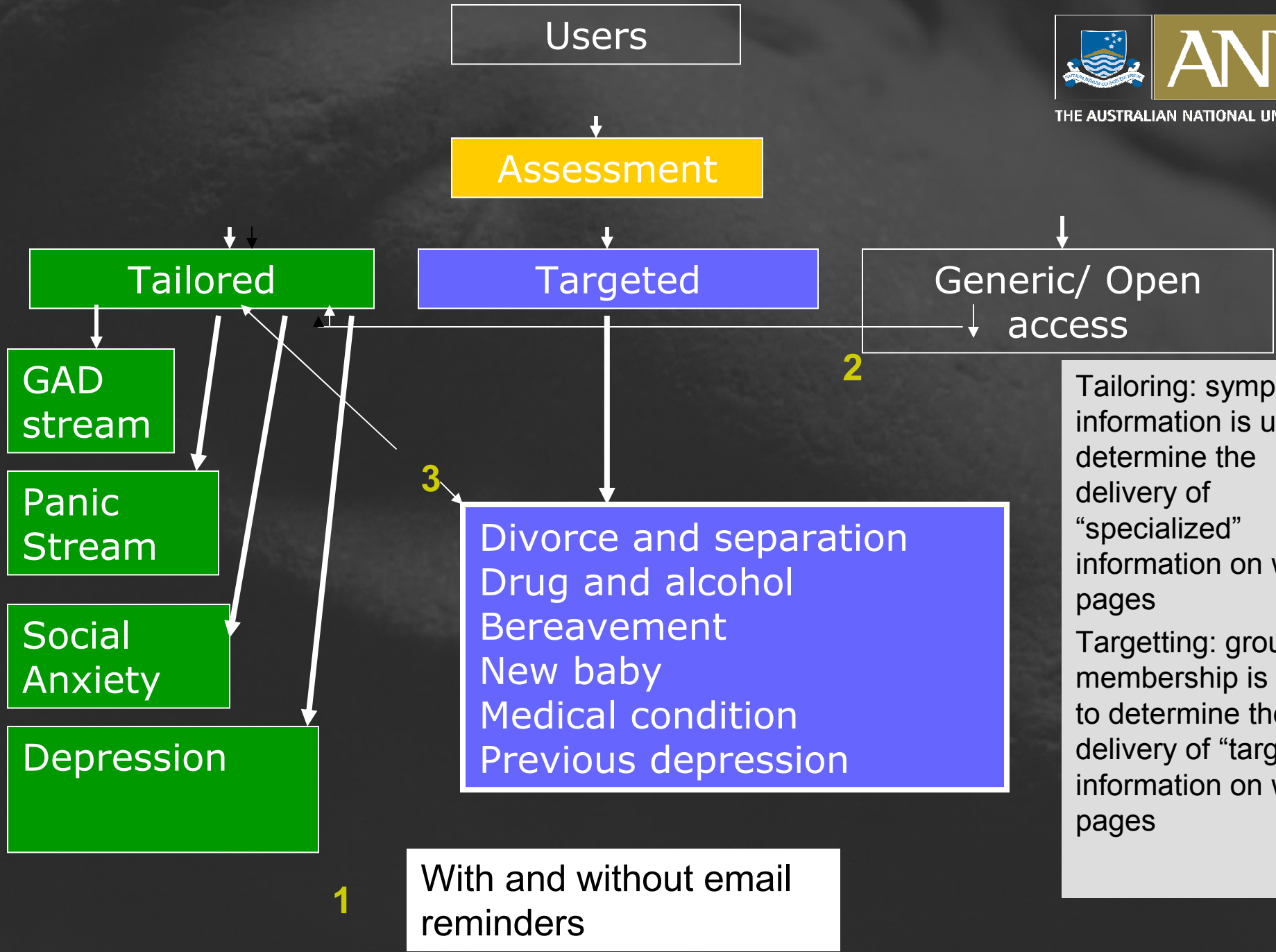
CBT

Relaxation

Activity

Series of RCTs

Effect of tracking/monitoring

Effect of open access or tailored program based on symptom profile

Effect of tailored program compared to tailored program plus targetted program

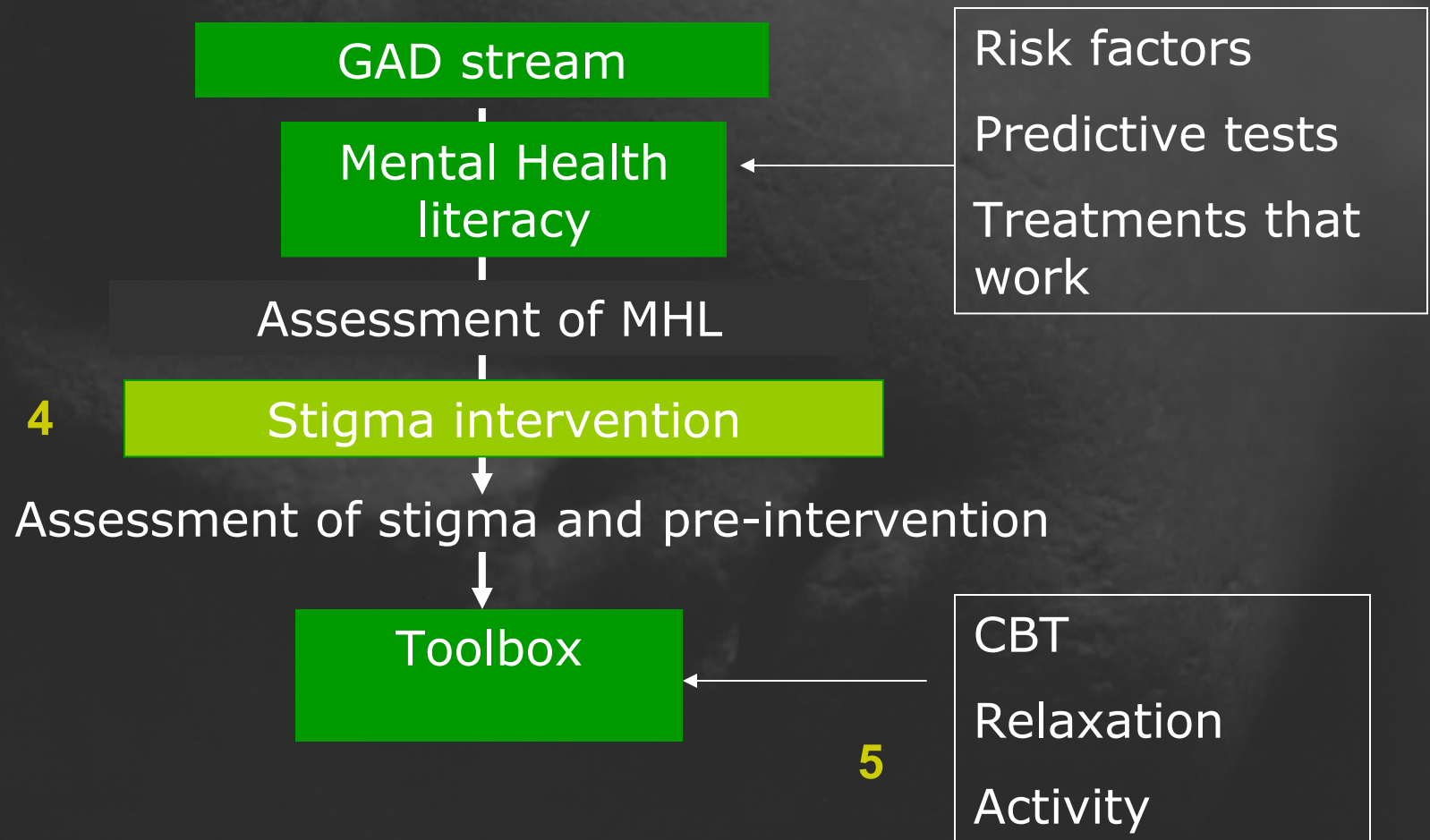Effect of stigma intervention for depression

Effect of components of the program; relaxation vs exposure vs physical activity.

Future Directions

Supporting international portals for distribution of effect e-applications

Linking open access websites into already existing health structures

Transforming current health systems

Improving continuity of care through consumer focused e-clinics

Developing financial sustainability

Doing better research

Moodgym and BluePages Contributors

Anthony Bennett, David Berriman, Kelly Blewitt, Kylie Brittliffe, Kimberley Evans, Cathy Frazer, Chloe Groves, David Hawking, Anthony Jorm, Claire Kelly, Betty Kitchener, Ailsa Korten, Alison Neil, Nick Newman, Liz Parkes, Ruth Parslow, Richard Pass, Sarah Vancea, Janine Walker, Tim Windsor