UNIVERSITY OF Southampton

LHF
London Housing Foundation

Homelessness, Social Exclusion & Health Inequalities 2015
4th March, 2015

Feasibility quasi-randomised control trial of a 12 session CBT / DBT intervention with adults living in hostels:
Early results and reflections on methods

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Background

- Small but growing evidence base in psychological interventions in homelessness
  - Evaluations
  - Output evidence
- Inform commissioning
- Improve services

Project

- Feasibility study funded by London Housing Foundation
  - £23,500
  - Path to an NIHR Efficacy and Mechanism Evaluation (EME) grant application
  - Low adherence to RCT CONSORT guidelines
- Questions:
  - Can this study be done? What are the practicalities?
  - Do we note any changes attributable to the intervention?
- Three time points
  - Pre, post, 3 – 6 month follow-up

Feasibility studies

To gather information on:

- standard deviation of the outcome measure to estimate sample size;
- willingness of participants to be randomised;
  willingness of clinicians to recruit participants;
  number of eligible patients, carers or other appropriate participants;
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance rates;
- availability of data needed
- time needed to collect and analyse data.

Project

- Three trained, accredited CBT therapists in Southampton
- Clinical Psychologist Westminster
- Clinical Psychologist Bristol
- Supervision by CI
- Adherence check by CI

- NHS multi site and University Ethics approvals
- GPs (and any other care workers) informed of intervention

Intervention

- 12 sessions of a formulation-based intervention based on cognitive behavioural therapy (CBT) and dialectical behaviour therapy (DBT) principles
- Intervention based on process research
  - Engagement
  - Emotion regulation skills
  - Interpersonal skills
  - Rumination
  - Cognitive challenge
  - Behavioural activation
- 'Guideline' manual

Participants

Southampton

- 46 people recruited (eight women, 34 men; aged 22 – 66)
- Three dropped out before time 1 assessment
- 15 randomised to control group, 16 to treatment (two blocks)
  - **Control group**
  - 1 moved to treatment group after time 1
  - 8 more lost before time 3
  - **Treatment group**
  - 32 started therapy (19 from randomisation, one moved group, 12 from unrandomised recruitment
  - 7 dropped out of therapy, most before session 3, no more data.

Participants

Bristol

- Four people recruited (all men, aged 33 – 51)
- No randomisation
- All completed therapy

Westminster

- Six people recruited (five men, one woman, aged 28 – 58)
- No randomisation
- All completed therapy, five data sets complete

Participants: Total

- 56 people recruited
- 15 randomised to control
- 16 randomised to treatment
- 22 treated but not randomised
- 16 dropped out (7 treatment, 9 controls)
- Missing data at T2 and T3

Participants: Reasons for missing data

- Death
- Prison
- Moved away
- Moved project and couldn't contact
- Contact but couldn't arrange convenient time
- No longer wanted to participate

Measures

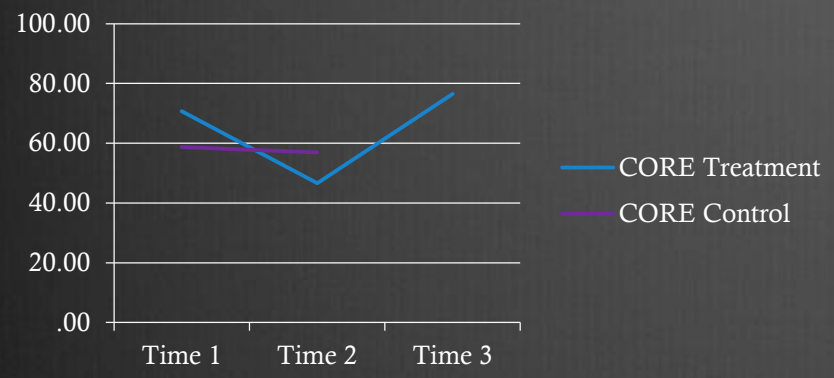
- Demographic and behavioural incidence measures

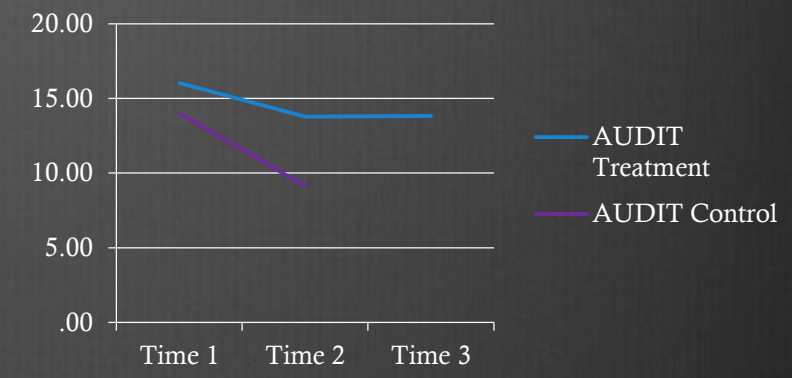
- Clinical Outcomes in Routine Evaluation (CORE-34)
- Alcohol Use Disorders Identification Test (AUDIT)
- Drug Abuse Screening Test (DAST-20)
- Impact of Events Scale –Revised (IES-R)
- Difficulties in Emotion Regulation Scale (DERS)
- University of Rhode Island Rating Scale (URICA)
- Maladaptive Behaviours Questionnaire (MBQ)

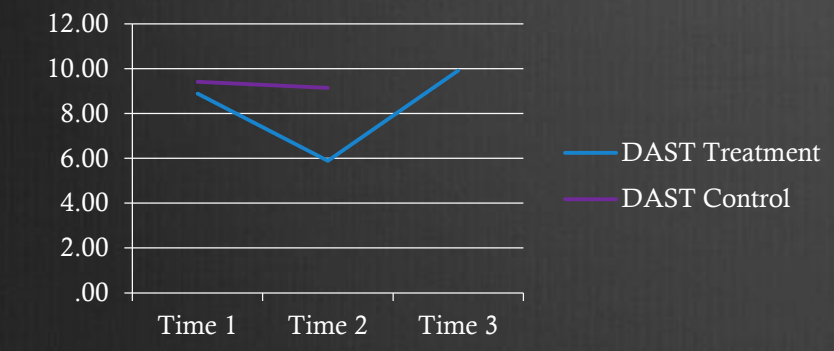
Results: Usable data

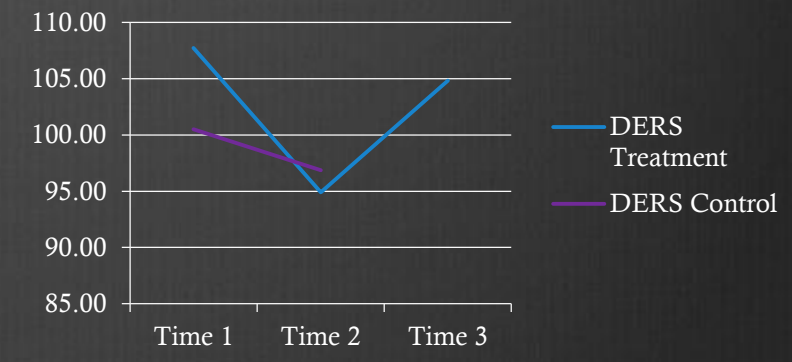
- Treatment arm:
  - 27 - 34 sets pre-therapy
  - 9 sets post-therapy
  - 11 sets 3 – 6 months follow-up
- Control arm (TAU)
  - 12 – 14 sets pre-therapy
  - 7 sets post-treatment
  - 6 sets 3 – 6 months follow-up
    - 2 sets very low relative to others; skewed data; FU excluded.

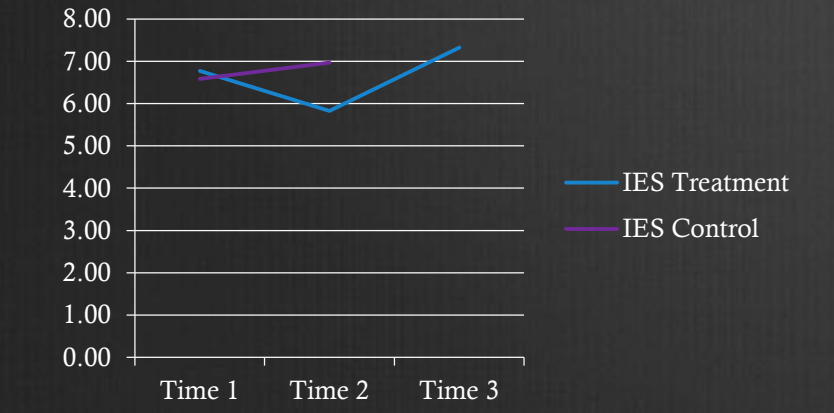
Results: Change

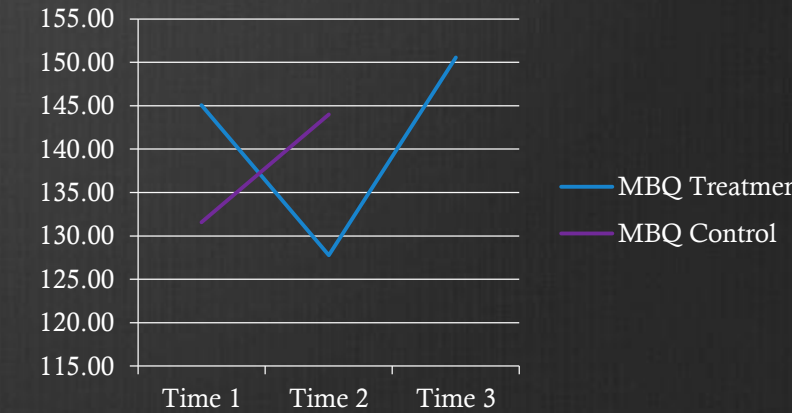












Results: Effect sizes

	Time 1		Time 2			
	Mean	SD	Mean	SD	Cohen's d	
CORE	70.5	27.02	46	24.85	**0.94**	L
AUDIT	16.88	12.17	13.36	9.05	**0.3**	M
DERS	100.63	23.74	94.5	26.45	**0.24**	S
DAST	7	6.33	6.38	6.7	**0.1**	S
IES	7.47	1.87	5.96	3.84	**0.5**	M
MBQ	138.88	31.1	127.5	32.52	**0.36**	M

Results

- CORE indicates treatment population in the moderate to severe clinical range (68 – 84)
  - Control in moderate range
- Treatment arm more severe on most measures
- Treatment arm makes gains pre-post then returns to baseline for follow-up
- Control arm variable, but no consistent change on most measures.
- Variance of measures generally high – heterogeneous population
- Effect sizes variable between small and large depending on measure

Results: conclusions

Small sample but:

- Some evidence that a 12 session CBT / DBT intervention improves mental health and associated measures over duration of the therapy
- No evidence that impact is sustained at follow-up
  - Little time to practice and generalise skills learned
  - Context-specific learning
- Need a longer intervention or 'boosters' to practice skills
- Involve hostel staff in generalising interventions

Feasibility: Practical issues

- Drop-out rate large (c. 60% for control, 30% for treatment)
- Drop-out rates of control group particularly difficult to manage
- Once past first 2 – 3 sessions, treatment group remained
- Lost some time 2 data due to RA not getting to participants, communication difficulties with hostels etc.
- Time 3 data lost due to losing contact with client
  - Death, prison, move geographically, different services, withdrew
- Client priorities and willingness to take part

Feasibility: Practical issues

- Fees mostly on therapy delivery; no trial manager and a temporary research assistant (RA)
- Recruitment was sporadic - depended on hostel staff, interest of clients, regular communication
- Randomisation in blocks due to recruitment
  - Anecdotally two people upset about randomisation
  - Broke randomisation for one of these
- Outcome measures acceptable; around an hour maximum
- Need dedicated trial manager to manage relationships with hostels and research assistants

Feasibility?

- **Yes, it can be done.**
- Trial manager
  - Funding
- Regular therapists, resilient RAs
- Gather T2 data after last session?
- Include local homelessness central agency (e.g. homeless healthcare team) for contacts.
- May need waiting list control.
- Effect size variable, depends on measure

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End

Questions?