

Introduction to the MRC Biostatistics Unit Hub in Trials Methodology Research and the HTMR Network

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Talk Outline

MRC

Hubs for Trials
Methodology Research

MRC Biostatistics Unit Hub

- MRC Biostatistics Unit Hub
- An example collaborative project

- Looking for **collaborative** projects
 - Want to be involved in the lifetime of a project
- Design, analysis and reporting of studies
- Interested in Statistical methods/design
 - training and implementation of statistical methods

Research Areas

MRC

Hubs for Trials
Methodology Research

MRC Biostatistics Unit Hub

- Initial research
 - Study design, multi-phase studies
 - Dose finding/escalating
 - Dose relationship estimation
- MRC Biostatistics Unit more broadly
 - Cost effectiveness analysis
 - Missing data
 - Cluster-randomised trials
 - Meta-analysis
 - Bayesian methods

MRC Biostatistics Unit Hub

MRC

Hubs for Trials
Methodology Research

MRC Biostatistics Unit Hub

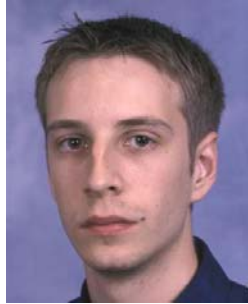
CCTC



Adrian
Mander



James
Wason



Michael
Sweeting



Angela
Talbot

Two PhD
students

Oct 2010



Deepak
Parashar



Simon
Bond

MRC Biostatistics Unit



Simon
Thompson



Linda
Sharples



Ian
White



Julian
Higgins



Vern
Farewell

Collaborative Project

MRC

Hubs for Trials
Methodology Research

MRC Biostatistics Unit Hub

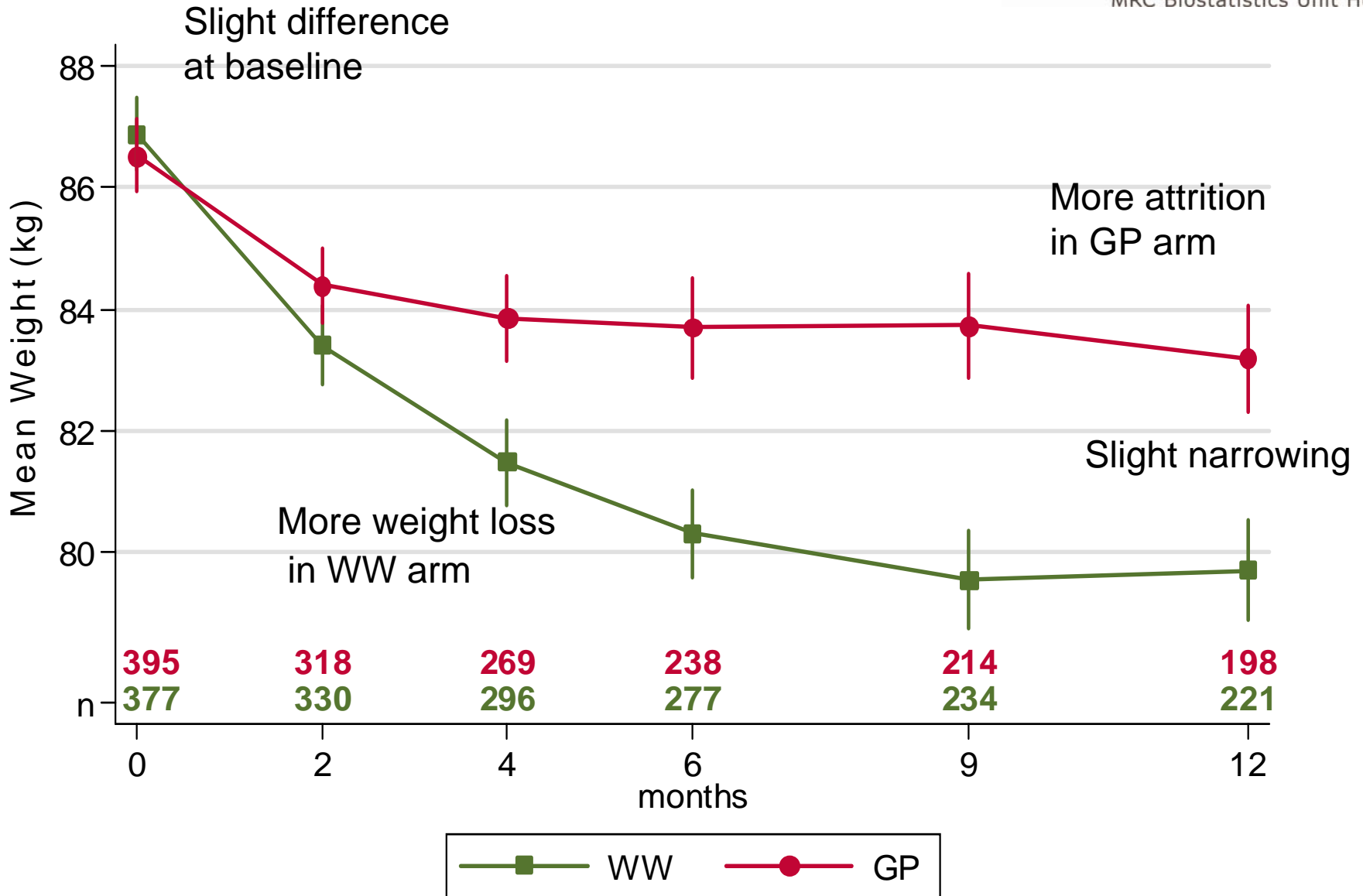
- Weightwatchers Trial, an unblinded parallel group trial
 - Comparing WW versus GP care
 - Primary outcome weight loss at 12 months
 - Inclusion criteria included body mass index from 27 kg/m² to 35 kg/m²
 - 50% dropout was anticipated
 - High risk that a bias would be introduced

ALL results are base on DRAFT data!

Collaboration

- Hub is working alongside the study team at MRC Human Nutrition Research Unit
 - Ashley Olson, Susan Jebb, Amy Ahern & Louise Aston
- We are getting help from BSU missing data experts
 - Dan Jackson, Shaun Seaman

“Mean” Profile



Possible analyses

- Primary outcome is the difference in weight loss between GP and WW arms at 12 months
- Completers
 - Analyse people with 12 month data only
- Baseline carried forward
 - Analyse all data but replacing missing data at 12 months with the baseline measurement
 - usual reporting method in obesity literature
- Mixed effects model
 - Analyse all the available data over the 12 months

Results

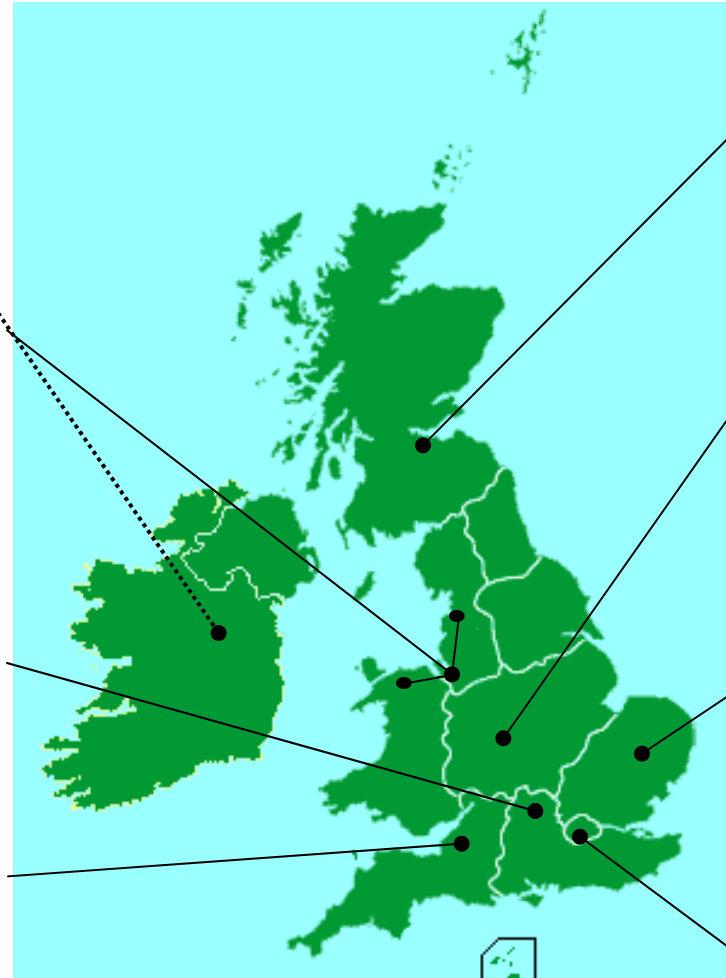
	Mean difference in weight loss (95% CI) GP - WW	
Baseline carried forward (n=772)	2.4kg	(1.7,3.1)
Completers (n=419)	3.7kg	(2.6, 4.8)
Mixed Effects Model (n=772)	3.5kg	(2.7, 4.2)

- Interested in setting up collaborative studies
 - Late phase clinical trials
 - Early phase experimental trials
- Contact us on
trials@mrc-bsu.cam.ac.uk

MRC Network of Hubs for Trials Methodology Research (HTMR)



MRC Biostatistics Unit Hub



All-Ireland HTMR

Northwest HTMR

Methods - design and analysis of early and late phase trials, patients' perspectives

Oxford HTMR (MRC CTSU)

Methods - trial conduct; IT in trial studies

ConDuCT HTMR

Methods - statistical methodology, design/conduct of challenging trials; HE, QoL and evidence synthesis.

Edinburgh HTMR

Methods - SRs, IPD, simulation, biomarkers

Midlands HTMR

Methods - statistical methodology, early phase trials and biomarkers, QoL & HE

Cambridge HTMR (MRC BSU)

Methods - statistical methodology, trial design, meta-analysis & HE

London HTMR (MRC CTU)

Methods - statistical methodology, trial conduct and meta-analysis