

REFERENCES AND FURTHER INFORMATION

McGurk, S. R., Twamley, E. W., Sitzer, D. I., McHugo, G., J. and Mueser, K. T. (2007). A Meta-Analysis of Cognitive Remediation in Schizophrenia. *American Journal of Psychiatry*, 164, 1791-1802.

Wykes, T., Reeder, C., Landau, S., Everitt, B., Knapp, M., Patel, A. and Romeo, R. (2007). Cognitive remediation therapy in Schizophrenia. *British Journal of Psychiatry*, 190, 421-427.

For further information about the study as part of the NEWMEDS (Novel Methods leading to New Medications in Depression and Schizophrenia), initiative please visit: www.newmeds-europe.com

WHO SUPPORTS NEWMEDS?

NEWMEDS is funded by the Innovative Medicines Initiative (IMI), a unique large scale public-private partnership between the European Union (represented by the European Commission) and the pharmaceutical industry (represented by the European Federation of Pharmaceutical Industries and Associations, EFPIA).

IMI JU aims to put Europe at the forefront of biopharmaceutical innovation and to support more efficient discovery and development of better medicines for patients. www.imi.europa.eu



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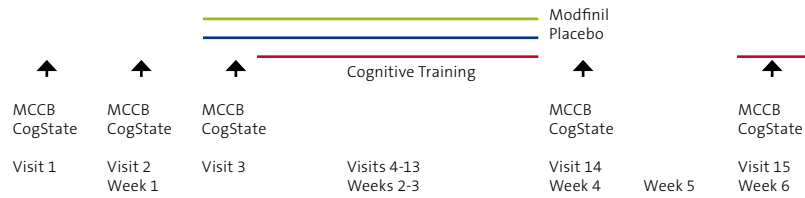
Cognitive Training and Modafinil for Cognition in Schizophrenia and Validating Cognitive Outcome Measures



DESIGN

Study 1

- 40 individuals with schizophrenia (20 Manchester site; 20 London site)
- Randomised Control Trial
- Randomised to Placebo – Modafinil
- **ALL** participants receive Cognitive Training- a set of computerised tasks similar to Brain Training



Study 2

- 40 individuals with schizophrenia
- **ALL** participants complete computerised cognitive batteries (MCCB and CogState) in Week 1 and Week 4



BENEFITS TO PARTICIPANTS

Study 1

- CT associated with improvement in 6 cognitive domains (McGurk et al., 2007)
- CT shown to exert a significant effect on psychosocial functioning (McGurk et al., 2007)
- CT demonstrated durable improvements in memory ► improvements in social functioning and self-esteem (Wykes et al., 2007)
- Reimbursed for travel, food, drink; compensated for time up to a maximum of £250 in total
- Many participants in CT studies find the tasks fun

Study 2

- Reimbursed for travel, food, drink; compensated for time up to a maximum of £80 in total

AIMS

- Combining cognitive enhancers (CE) with cognitive training (CT) will improve cognition more than CE or CT alone
- Validate computerised cognitive battery of neuropsychological tests (CogState) against existing paper and pen battery (MCCB)

EXCLUSION CRITERIA

- Alcohol or substance abuse or dependence
- Treatment with Clozapine, Modafinil, Cyclosporine, Phenytoin
- Treatment with psychotropic agents known to affect cognition
- Treatment with anticoagulants, tricyclic antidepressants
- Neurological disorder or cardiac problems
- Any known drug allergies, including sensitivity to Modafinil
- Prior participation in a clinical trial of any psychotropic medication in the last 2 months

INCLUSION CRITERIA

- Schizophrenia or schizoaffective disorder =/+ 1 year
- 18 to 50 years
- Clinically stable in a non-acute phase
- Treatment with stable doses of atypical antipsychotics
- Not pregnant nor breastfeeding
- Read and write in English