

Training to Give Informed Consent to Medication

The Effects of Training on the Ability of Adults with an Intellectual Disability to Give Informed Consent to Medication.

Training to Give Informed Consent to Medication

Abstract

Background This study had two aims: to investigate the capacity of individuals with intellectual disabilities to make decisions about their medications, and to evaluate whether the provision of training (information) sessions on medications would increase their capacity.

Method 28 adults (18 male and 10 female), with a mild to moderate intellectual disability were included in this study and they were taking either Epilim, Metformin or Haloperidol medications. The participants were split into groups that comprised of participants taking the same medications. Each of the groups received three training sessions on their own medications. Capacity to consent was measured by the A-ACQ, which was specially adapted for each medication type from the original measure (ACQ). Receptive language ability was measured by the BPVS-II.

Results A two factor mixed ANOVA analysis indicated that the provision of training had improved the capacity of the participants to give informed consent to taking their medications. Analysis using Pearson's correlations indicated that increased levels of receptive language ability correlated with greater increases in the ability to give informed consent to taking medication.

Conclusions The provision of information that is formatted in a way that individuals with intellectual disabilities can understand may be a useful way to increase knowledge on medications. Further research that investigates the provision of information with larger samples is warranted.

Keywords: training, adults, intellectual disability, capacity, consent, medication

Training to Give Informed Consent to Medication

Introduction

In the past people with intellectual disabilities often had their decisions made for them (Murphy & Clare, 2003), despite the fact that in most developed countries there was a general respect for autonomy, and most non-disabled adults were assumed to be competent and were deemed to have the right to accept or refuse treatment, even if their decision appeared to be irrational (Nicholls, 1993; Grisso and Appelbaum, 1998). More recently, people with intellectual disabilities have been asserting their right to make their own decisions and, in England and Wales, this right is enshrined in law for those with capacity, under the Mental Capacity Act 2005 (Department for Constitutional Affairs, 2007).

Capacity and informed consent

Determining capacity to give informed consent to treatment is complex, and needs to consider an individual's rights to make their own decisions as well as the need to protect them from any potential harm (Wong, Clare, Gunn & Holland, 1999). Historically, three approaches have been utilised to assess an individual's capacity to consent: the diagnostic, outcome, and functional approaches (Murphy & Clare, 2003). The functional approach is the most frequently used approach to establish capacity, and is now enshrined in law in England and Wales in the MCA 2005. This approach establishes whether an individual's skills, abilities and knowledge are sufficient to enable them to make a decision in a particular situation (Grisso, 1986). A functional framework approach is decision-specific and allows for fluctuations in capacity and for the possibility of increasing capacity to consent (Murphy & Clare, 2003).

Evaluation of informed consent

Training to Give Informed Consent to Medication

Evaluating capacity to give informed consent, in England and Wales, requires the assessment of whether a person can understand and retain information pertinent to the decision; whether he or she can utilise and manipulate that information and whether he or she can communicate a decision (Department of Constitutional Affairs, 2007). Individuals with intellectual disabilities may have difficulties in the comprehension of information regarding treatment (Arscott, 1997). The more severe the person's intellectual disability, the more impaired that individual is likely to be in understanding information (Morris, Niederbuhl & Mahr, 1993; Arscott, Dagnan & Stenfert Kroese, 1999; Cea and Fisher, 2003). Adults with intellectual disabilities may also struggle with understanding and appreciating risks and benefits of treatment and alternatives available, weighing the alternatives up, and understanding their right to say no (Cea and Fisher, 2003). Their thinking processes may be concrete and they may have poor problem-solving abilities, as well as often having little experience of choice-making (Curran & Hollins, 1994).

Medication and learning disabilities

Adults with intellectual disabilities are more likely to experience mental illness than non-disabled adults and they are prone to develop chronic health problems, epilepsy, and physical and sensory disabilities (DOH, 2001). They are often prescribed a range of medications both for these conditions and to reduce challenging behaviours, for example, aggression. The majority of research on this population regarding medication has focused on the use of psychotropic medications (Arscott, Stenfert Kroese & Dagnan, 2000; Crossley & Withers, 2009) and there appears to be a high occurrence of the prescribing of these medications (Robertson, Emerson, Gregory, Hatton et al, 2000; Stenfert Kroese, Dewhurst & Holmes, 2001) despite

scant investigation of the occurrence and frequency of side-effects of medication in the population with intellectual disabilities.

Knowledge of medication

Individuals with intellectual disabilities, like anyone else, should be given information about the function of their medication, reasons for prescription, side-effects, risks and benefits and alternatives to taking the medication. Limited research exists on the knowledge this population possesses about their medication. One study that investigated the amount of knowledge that individuals with intellectual disabilities have about their medication found that most participants knew the administration time of their medication, consequences for not taking it, reasons for taking it and the function of medication but, they appeared to lack knowledge on the side-effects and alternatives to medication (Arscott et al., 2000). However, the number of participants used was small (n=30) and caution needs to be taken in the generalisation of the results. However, Crossley & Withers (2009) in a small qualitative study (n=8) reported similar findings.

Strydom, Forster, Wilkie, Edwards & Hall (2001) reviewed information leaflets that are supplied with medications and designed some specifically for individuals with intellectual disabilities (Strydom et al., 2001). However, their randomised trial of the effects of these leaflets on knowledge about medication suggested that the leaflets did not improve knowledge (Strydom & Hall, 2001). Heslop et al. (2005) and Fretwell & Felce (2007) have found that carers also seemed to lack knowledge about reasons why the disabled person in their care was prescribed medication and they lacked knowledge about its side-effects. Most of the carers in the Heslop et al. study expressed satisfaction with the knowledge they possessed, though

Training to Give Informed Consent to Medication

some wanted to know more about the function of the tablets, duration of treatment and potential risks (Heslop et al., 2005). Few of the carers in Fretwell & Felce (2007) however were satisfied with the information they had and most felt they required training. Larger scale postal surveys of staff opinions and knowledge of medication have produced similar calls for further training for staff in intellectual disability services (Christian, Snyckerski, Singh & Poling 1999).

Aims of this research

The present study had two aims: to investigate the capacity of people with intellectual disabilities to make decisions about their medication and to evaluate whether the provision of training (information) sessions on medication to people with intellectual disabilities would increase their capacity.

Method

This study was given ethical approval from the relevant NHS ethical body at the time (Central Office for Research Ethics Committees - COREC). The manager of the local Social Services (SS) department dealing with intellectual disability services also gave approval for the research to take place.

Participants

The inclusion criteria were: adults with a mild to moderate intellectual disability, who were aged 18 years or over, males or females, currently taking either Metformin (diabetic), Haloperidol (psychotropic) or Epilim (anti-convulsant) medications. Participants were excluded if they could not consent to participate in the study, if they were not taking medication or were on multiple medications. It should be noted that participants were only included if they had capacity to give their consent to participate in the study.

Training to Give Informed Consent to Medication

After consultation with community nurses and day centre staff (see Procedure), in a Social Services run intellectual disability service, 39 potential participants were identified, who met the above criteria for ID, age and medication. However, four withdrew their consent, and a further seven were not suitable for inclusion because their level of intellectual disability was too severe and / or their communication difficulties were too extreme for them to be able to consent to the research. Therefore, 28 adults, with mild to moderate intellectual disabilities were recruited.

Measures

British Picture Vocabulary Scale (BPVS-II - Dunn et al., 1997).

The BPVS-II, consisting of 168 items, is a standardised measure of language comprehension. A list of words is read to the individual and, for each word, they have to choose from four possible pictures and point to the picture that they believe best depicts the word given (all pictures are line drawings). A receptive vocabulary age equivalent score is then obtained. Good reliability has been reported (median Cronbach's alpha 0.93, median split-half 0.86). The BPVS-II is assumed to have validity as it is derived from the original version; however, this has not been independently established. Nevertheless, it correlates closely with IQ scores (Dunn et al., 1997; Glenn & Cunningham, 2005).

Adapted – Assessment of Capacity Questionnaire (A-ACQ - Adapted from Morris et al., 1993; Arscott et al., 1999).

The original measure (Morris et al., 1993) incorporated three hypothetical vignettes, presented in the second person ("you"), that described individuals being offered behavioural, surgical and medical interventions. Questions were asked which aimed to assess an individual's understanding of the presenting problem, the

Training to Give Informed Consent to Medication

procedure, risks, benefits and alternatives. A scoring schedule was employed that measured the minimum levels of knowledge and voluntariness that was needed to determine whether an individual was able to give informed consent. The original ACQ appeared to be a reliable measure with highly significant inter-rater reliability (kappa coefficient 0.79) (Morris et al., 1993). The measure was slightly adapted by Arscott et al., 1999, and it also appeared to have face and content validity (Arscott et al., 1999).

The adapted ACQ (A-ACQ) utilised in this study, was altered from Arscott et al.'s version so that it incorporated vignettes on three different medications (Haloperidol, Metformin and Epilim) in order to ensure that the vignette matched the participant's circumstances (each participant was only presented with one vignette, the one that matched their medication). 16 (57.1%) participants were taking Epilim, five (17.9%) participants were taking Haloperidol and seven (25%) had been prescribed Metformin medications.

The vignettes were presented in the first person, to make the information relevant to the participant. Pictures accompanied the scenarios and were presented alongside the information. Questions followed the information to assess an individual's knowledge and understanding of the problem, knowledge and understanding of the treatment (medication), risks, benefits, rights, choices and alternatives (for details of the questions, see Table 1). Scores for each question ranged between zero and two, depending on the degree to which the answer showed a good comprehension of the material. The maximum possible score was 14. For a participant to be judged as having capacity to consent to their medication, they had to gain a score of at least one point on each of the questions on the A-ACQ. Test re-test

reliability was excellent (see Results section). (Copies of the A-ACQ may be obtained from the first author).

Table 1 about here

Procedure

The chief investigator (CI) visited day care provisions and residential homes for adults with intellectual disabilities, in conjunction with a community nurse who normally visited potential participants, to initially introduce the project. A member of the day service staff or a carer (in residential homes) was also present at these meetings with the CI. Specifically adapted information sheets giving both written and pictorial information about the study were given to participants at these visits. Each individual was given one week to decide if they wanted to participate and staff were asked to help them understand and consider the information sheet. Individuals who expressed an interest in being included in the study, attended a group with other potential participants at a convenient time for them. The project was explained again in depth and written consent was obtained by the CI and a community nurse. The CI ensured that every participant fully understood the nature of the research, the risks and benefits of participating and that they could withdraw their consent at any time. The carer and General Practitioner (GP) of each of the participants who gave their consent, were also sent letters and information sheets about the study. None of the participants was under the care of a Psychiatrist.

At the first meeting with each participant, following consent, The British Picture Vocabulary Scale-II (BPVS-II) (Dunn, Dunn, Whetton & Burley, 1997) was administered to assess the participant's language comprehension. Background and demographic information were also recorded (gender, age, residential setting, length

Training to Give Informed Consent to Medication

of time on medication). The participant's ability to give informed consent to their own medication was then assessed using the adapted version of the ACQ.

After a period of two weeks (a 'control' period), the participants completed the A-ACQ for a second time before intervention, in order to investigate whether the experience of the first assessment and having time to consider information from baseline assessment would produce any significant changes at re-assessment. The participants were then split into groups that comprised participants taking the same medication. Each of the groups then received three training sessions on their own medications: this was provided in a group-training format (by the first author). Participants were told that they could invite their carers to attend as well, if they wished, but none did.

The content of the training included: function of medication, possible side-effects, risks, benefits and alternatives to medication; employing pictorial aids as necessary. In session one, the reasons for the prescribing of each medication, the physiological effects and any possible side-effects were discussed. Session two included a review of all the positive and negative things that could occur if the individual continued to take their medications. Session three incorporated a discussion on the alternatives available to the person instead of taking their medication, for example, avoiding alcohol or flashing lights for those taking anti-epileptics. The Mental Capacity Act was reviewed and capacity to consent was explained. An emphasis was placed on the correct information about medication being given to the individual and the rights of the individual to ask other relevant professionals (GP) for further information or clarification. It was stressed that each person who is deemed to be capacitous had the right to take or refuse their prescribed medications. There was no take-home information.

Training to Give Informed Consent to Medication

Capacity to consent was then measured again, two weeks after training, using the A-ACQ.

Data analysis

Data were explored (using the Statistical Package for the Social Science (SPSS) Version 14.0) to examine skew, kurtosis and normality. BPVS-II skew was 0.93 and kurtosis -1.23 ; A-ACQ (baseline) skew was -1.24 and kurtosis -1.04 ; A-ACQ (first re-assessment) skew was -1.33 and kurtosis -0.81 ; A-ACQ (second re-assessment) skew was -1.17 and kurtosis -0.46 . The data were thus normally distributed and parametric statistics were used.

Pearson's correlations were carried out to investigate the associations between all of the following: the BPVS-II scores, A-ACQ (baseline) assessment scores, the A-ACQ scores at first and second re-assessment, and the change in A-ACQ scores from first to second re-assessment.

A two factor mixed factorial analysis of variance (ANOVA) was used with the A-ACQ scores to investigate significant interaction effects between the groups and occasions. The type of medication (groups) was the between subject factor and the A-ACQ scores (occasions) was the within subject factor.

The significance level used throughout was $p < 0.01$ in view of the number of analyses conducted, in order to avoid type 1 errors.

Results

Demographic information

The age range of the 28 participants was between 20 to 56 years (mean = 38.71 years, SD = 10.41 years) and there were 18 males and ten females. The majority

Training to Give Informed Consent to Medication

of participants (13) resided in supported living, while 6 lived in residential homes, 6 lived with their own family, one was living alone and one in a family placement.

Medication

16 (57.1%) participants were taking Epilim, five (17.9%) participants were taking Haloperidol and seven (25%) had been prescribed Metformin medications. The participants had been taking their medications for an average duration of 8.46 years (range = 1-30 years). On average, participants were taking Epilim for 12.63 years (range = 1-30 years), Haloperidol for 2.4 years (range = 1 to 4 years) and Metformin for 3.29 years (range = 1-5 years).

The mean BPVS-II raw score for the participants was 70.46 (SD = 5.51, range of scores = 63 to 81). The mean vocabulary age equivalent score was 6 yrs 8 mths (range 6yrs 2 mths to 7yrs 11mths).

The range of scores on the A-ACQ at baseline assessment was one to seven (mean score = 4.61, SD = 2.06). The range of scores at first re-assessment before treatment (control) was one to seven (mean score = 4.68, SD = 1.96). The mean score on this measure at second re-assessment (post-intervention) was 6.61 (SD = 2.23), with a range of scores between two and ten.

Receptive language comprehension ability and informed consent

It was hypothesised that individuals with intellectual disabilities who had a higher level of receptive language comprehension, as measured by the BPVS-II, would have gained higher scores on the A-ACQ. A series of parametric correlations (Pearson's correlations) were performed to test for significant associations between

Training to Give Informed Consent to Medication

the BPVS-II scores and the pre-training (baseline assessment), first re-assessment and second re-assessment (post-intervention) A-ACQ scores.

Highly significant positive correlations (all two-tailed, all $n=28$) were found between the BPVS-II scores and scores on the A-ACQ baseline assessment ($r = 0.903$, $p<0.01$), A-ACQ first re-assessment ($r = 0.873$, $p<0.01$), and A-ACQ second re-assessment ($r = 0.915$, $p<0.01$). The correlation between the BPVS-II score and the change in A-ACQ scores (from first re-assessment to second re-assessment, i.e. after training) was not quite significant ($p=0.033$).

Association of scores on A-ACQ

A correlation was performed on the scores on the A-ACQ baseline assessment (pre-treatment) and the scores at first (control) and second re-assessment (post-treatment). Highly significant positive correlations were found (all two tailed, all $n=28$) between scores at baseline assessment and first re-assessment ($r = 0.984$, $p<0.01$) and between baseline and second re-assessment ($r = 0.939$, $p<0.01$). In addition there was significant correlation between the first re-assessment and second re-assessment ($r = 0.933$, $p<0.01$).

Provision of training

It was hypothesised that the provision of training on the participant's medication would increase the ability of the participants to give informed consent to their medication. The mean total scores (and standard deviations) for each type of medication on each occasion of the A-ACQ measurement are shown in Table 2. The scores increased from baseline assessment to second re-assessment (post-intervention) for all of the three medication groups.

Table 2 about here

For the statistical analysis, Mauchly's test indicated that the assumption of sphericity had been violated (chi-square = 12.53, $p < 0.01$); therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity (epsilon = 0.71). The results indicated that the scores on the A-ACQ's (baseline, first and second re-assessment) differed significantly, $F(1.42, 35.55) = 180.60$, $p < 0.01$; partial eta squared = 0.88, indicating a large effect. The results indicated that there was no significant interaction effect between occasions (of assessment) and medication group: $F(2.84, 35.55) = 4.21$, $p > 0.01$. The between subjects effects (medication group) was also not significant: $F(2, 25) = 0.054$, $p > 0.01$.

Post-hoc tests (Bonferroni) revealed that there was no significant difference between scores on the A-ACQ at baseline assessment and at first re-assessment (control) ($P > 0.01$) when no training (intervention) had been administered. However, there was a highly significant difference between scores at baseline when compared to scores at second re-assessment (after the training had been implemented) ($P < 0.01$). There was also a highly significant difference between scores at first re-assessment (control) and second re-assessment (post-training). This suggested that the provision of training (information) had increased the participants' knowledge of their medications, as measured by the A-ACQ and subsequently, increased their capacity to give informed consent to taking medication.

Training to Give Informed Consent to Medication

The scores on the A-ACQ across the medication groups improved on all the questions after training, except for question six, where the scores remained unchanged (see Table 3).

Table 3 about here

Capacity to consent to medication

For a participant to be judged as having capacity to consent to their medication, they had to gain a score of at least one point on each of the questions on the A-ACQ. Overall, of the 28 participants, only two (7%) participants were judged able to consent to their medication at baseline and first re-assessment. This increased to six (21%) participants who were judged able to consent to their medications at the second re-assessment, after training, which fell just short of a significant increase (Fisher's exact test $p=0.04$).

Discussion

This study investigated whether the provision of training (information) on medication would increase the capacity of people with mild to moderate intellectual disabilities to give informed consent to taking their medication. The 28 participants included in this study were taking either Epilim, Metformin or Haloperidol medications. Possible improvements in knowledge included: the function of medication, possible side-effects, risks, benefits and alternatives to medication. It was also hypothesised that individuals who had a higher level of receptive language comprehension would have gained higher scores on the A-ACQ. With respect to the research hypotheses, analysis using Pearson's correlations showed highly significant

Training to Give Informed Consent to Medication

correlations were found between BPVS-II scores and scores on the A-ACQ at baseline (pre-training), first (control) and second re-assessment (post-treatment), indicating that those with better verbal comprehension were more likely to have capacity to consent to treatment, as others have also found (Arscott et al, 1999). Analysis on the A-ACQ scores using a two factor mixed factorial ANOVA indicated that there was no significant difference in the scores between medication groups on the A-ACQ, showing that groups did not differ on the A-ACQ before or after training was provided.

However, a highly significant difference was found on the A-ACQ between scores at baseline and those at second re-assessment. There was also a highly significant difference between scores at first re-assessment (control) on the A-ACQ and second re-assessment. This suggested that the provision of training (information) had increased the participants' knowledge of their medications, as measured by the A-ACQ and consequently, had increased their capacity to give informed consent to taking their medication. This increase in knowledge was weakly correlated with the participants' verbal comprehension, suggesting that it may be that those with higher verbal comprehension may benefit more from training.

An overall increase in scores on the A-ACQ was found after training had been provided across the three medication groups, except for in question 6 (whether they should carry on taking the tablets), which remained predominantly unchanged. It is difficult to know why this remained unchanged but it is possible that the wording of the question influenced participants, as it reminded them that their doctor had said they should take the tablets and there is a very clear power differential between the participants and their GP, so they may have been reluctant to contradict their GP's opinion.

Training to Give Informed Consent to Medication

A stringent criterion was employed to judge if a participant had capacity to consent to their medication before and after training was given. For an individual to be judged capacitous they had to score one point on each of the questions on the A-ACQ. If a score of zero was given for any of the questions, the participant was not included as having capacity. Increases in capacity occurred in all three groups after the provision of training, an overall increase from 1 participant (4%) to 6 participants (21%). The precise criteria used are of course debatable but the scoring criteria and the judgment of capacity utilised in this study were similar to those used by Arscott et al. (1999), who also found a correlation between capacity to consent and verbal ability. Their study used the ACQ questionnaire and also a scoring system that allowed a participant to score 0, 1 or 2 on each question. For an individual to be judged as capacitous in their study, they had to gain at least one point on each of the questions on the ACQ. This scoring procedure was also adopted in this study as it was thought more sensitive than the one employed in the original three vignettes used by Morris et al. (1993), where a participant could only score zero or one on the assessment.

People with intellectual disabilities have a well-recognised raised risk of co-morbid health problems (DoH, 2001) and yet there is a lack of research on the safety of medication within this population. It is therefore important that alternatives to medication, for example, psychological treatment like anger management programmes, are offered as alternatives for the individual (Reiss & Aman, 1998), and it is particularly important for people to make their own decisions regarding taking medication. Recent audits of capacity and consent in those individuals with intellectual disabilities taking medication have indicated that this is a frequently neglected issue (Unwin & Shoumitro, 2008; Roy, Jain, Roy, Ward et al., 2011).

Training to Give Informed Consent to Medication

The results of this study are encouraging in that, unlike Strydom and Hall's study (2001), the provision of detailed information formatted in a way that individuals with intellectual disabilities can understand appeared to be a useful way to raise knowledge on medications. Individuals with intellectual disabilities, like anyone else, should be given information about the function of their medication, reasons for prescription, side-effects, risks and benefits and alternatives to taking the medication. Such information may need to be presented in substantial training sessions, as in this study, rather than simply by leaflets (as in Strydom & Hall, 2001). The training materials in this study were very accessible, the information was straightforward and clear, and participants were encouraged to ask questions and seek clarification. This is likely to be more effective than a leaflet.

The participants in this study had been receiving their medication for many years. They may have simply continued from habit. What is important in the future is for medical and nursing staff to provide this kind of information and training before people begin taking medication, or at least shortly afterwards if the situation is considered urgent, so that people with intellectual disabilities get a realistic chance of making their own decisions.

In terms of the strengths of this study, it is important to note that it concerned assessing capacity in people with intellectual disabilities in a real situation (like in Wong et al, 2000), rather than simply assessing capacity using fictional vignettes (as in Morris et al, 1993; Arscott et al, 1999; Cea & Fisher, 2003). Moreover it aimed to increase people's capacity to consent to treatment, using training sessions, something several researchers have felt would be useful but has not been done as yet. There were some methodological limitations in the study however: the number of participants recruited was small and caution needs to be applied when generalising the results.

Training to Give Informed Consent to Medication

There was no formal control group used to compare the group that received training with a group of participants that did not receive this intervention. However, this was addressed by having a re-assessment of the participants after a short period of time to ensure there were no significant changes on the A-ACQ scores when no training had been provided. Another limitation is that there was no follow-up assessment to assess if the improvements in knowledge of medication were maintained after the training period had ceased. Moreover, the researchers rating the answers to questions were not blinded to the participant's receipt of training, and only participants able to consent to the research were included, so we know very little about possible changes with training for those unable to consent to research. In terms of future studies, it would be useful to carry out the training package with a larger group of participants, randomising the participants to training and no-training groups, and keeping the raters blind to participants' groups. This could be achieved by recruiting participants across multiple sites and including a wider range of medications.

It would also be important to offer some training to carers, as it has been reported that carers seemed to lack knowledge about reasons why the disabled person in their care was prescribed medication and the relevant side effects. The majority of carers in several studies stated that they believed that they did not have adequate information (Christian et al, 1999; Heslop et al., 2005; Fretwell & Felce, 2007).

References

- Arscott, K. (1997). Assessing the capacity of people with learning disabilities to make decisions about treatment. *Tizard Learning Disability Review*, 2, 17-28.
- Arscott, K., Dagnan, D. & Stenfert Kroese, B. (1999). Assessing the ability of people with a learning disability to give informed consent to treatment. *Psychological Medicine*, 29, 1367-1375.
- Arscott, K., Stenfert Kroese, B. & Dagnan, D. (2000). A study of the knowledge that people with intellectual disabilities have of their prescribed medication. *Journal of Applied Research in Intellectual Disabilities*, 13, 90-99.
- Beauchamp, T. L. & Childress, J.F. (2001). Informed consent in psychotherapy. *American Journal of Psychiatry*, 158, 4-10.
- British Psychological Society. (2006). *Assessment of Capacity in Adults: Interim Guidance for Psychologists*. Leicester: British Psychological Society.
- Cea, C.D. & Fisher, C.B. (2003). Health care decision-making by adults with mental retardation. *Mental Retardation*, 41, 78-87.
- Christian, L., Snyckerski, S.M., Singh, N.N. & Poling, A. (1999). Direct service staff and their perceptions of psychotropic medication in non-institutional settings for people with intellectual disability. *Journal of Intellectual Disability Research*, 43, 88-93.
- Crossley, R. & Withers, P. (2009) Antipsychotic medication and people with intellectual disabilities : Their knowledge and experiences. *Journal of Applied Research in Intellectual Disabilities*, 22, 77-86.
- Curran, J. & Hollins, S. (1994). Consent to medical treatment and people with

Training to Give Informed Consent to Medication

learning disabilities. *Psychiatric Bulletin*, 18, 690-693.

Department of Health. (2001). *Valuing People: A New Strategy for Learning*

Disability for the 21st Century. London: Department of Health.

Dunn, L. M., Dunn, L. M., Whetton, C. & Burley, J. (1997). *The British Picture*

Vocabulary Scale – Second Edition. Windsor: NFER- NELSON.

Ellis, N. R., Deacon, J. R. & Woodridge, P. W. (1985). Structural memory deficits of

mentally retarded persons. *American Journal of Mental Deficiency*, 89, 393-402.

Fretwell, C. & Felce, D. (2007) Staff knowledge of the side effects of anti-psychotic

medication. *Journal of Applied Research in Intellectual Disabilities*, 20, 580-585.

Glenn, S. & Cunningham, C. (2005). Performance of young people with Down's

Syndrome on Leiter-R and British Picture Vocabulary Scales. *Journal of Intellectual Disability Research*, 49, 239-244.

Grisso, T. (1986). *Evaluating Competencies: Forensic Assessment and*

Instruments. New York. Plenum Press.

Grisso, T. & Appelbaum, P. (1998). *Assessing Competence to Consent to Treatment:*

A Guide for Physicians and Other Health Professionals. New York. Oxford University Press.

Heslop, P., Folkes, L. & Rodgers, J. (2005). The knowledge people with learning

disabilities and their carers have about psychotropic medication. *Learning Disability Review*, 10, 10-18.

Morris, C. D., Niederbuhl, J. M. & Mahr, J. M. (1993). Determining the capability of

individuals with mental retardation to give informed consent. *American Journal of Mental Retardation*, 98, 263-272.

Training to Give Informed Consent to Medication

- Murphy, G. & Clare, I.C.H. (2003). Adults capacity to make legal decisions. In Bull R. & Carson D. (Eds), *Handbook of Psychology in Legal Contexts (2nd Edition)*. Wiley and Sons.
- Nicholls, M. (1993). Consent to medical treatment. *Family Law*, 23, 30-33.
- Reiss, S. & Aman, M. G. (1998). *Psychotropic Medications and Developmental Disabilities: The International Consensus Handbook*. Ohio: The Ohio State University Nisonger Centre.
- Ridout, S., Waters, W. E. & George, C. F. (1986). Knowledge of and attitudes to medicines in the Southampton community. *British Journal of Clinical Pharmacology*, 21, 701-712.
- Robertson, J. Emerson, E. Gregory, N., Hatton, C., Turner, S., kessissoglou, S. & Hallam, A. (2000). Receipt of psychotropic medication by people with intellectual disability in residential settings. *Journal of Intellectual Disability Research*, 44, 666-676.
- Roy, A., Jain, S., Roy, A., Ward, F., Richings, C., Martin, M. & Roy, M.,(2011). Improving recording of capacity to consent and explanation of medication side effects in a psychiatric service for people with learning disability: audit findings. *Journal of Intellectual Disabilities*, 15, 85-92
- Smith, C., Felce, D., Ahmed, Z., Fraser, W. I., Kerr, M., Kiernan, C., Emerson, E., Robertson, J., Allen, D., Baxter, H. & Thomas, J. (2002). Sedative effects on responsiveness: evaluating the reduction of antipsychotic medication in people with intellectual disabilities using a conditional probability approach. *Journal of Intellectual Disability Research*, 46, 464-471.
- Stenfert Kroese, B., Dewhurst, D. & Holmes, G. (2001). Diagnosis and drugs: help or hindrance when people with learning disabilities have psychological

Training to Give Informed Consent to Medication

problems? *British Journal of Learning Disabilities*, 29, 26-33.

Strydom, A., Forster, M., Wilkie, B. M., Edwards, C. & Hall, I. S. (2001).

Patient information leaflets for people with learning disabilities who take psychiatric medication. *British Journal of Learning Disabilities*, 29, 72-76.

Strydom, A. & Hall, I. (2001) Randomized trial of psychotropic medication information leaflets for people with intellectual disability. *Journal of Intellectual Disability Research*, 45, 146-151.

Unwin, G.L. & Shoumitro, D. (2008) A multicentre audit of the use of medication for the management of behavioural problems in adults with intellectual disabilities. *British Journal of Learning Disabilities*, 36, 140-143.

Wong, J. G., Clare, I. C. H., Gunn, M. J. & Holland, A. J. (1999). Capacity to make health care decisions: its importance in clinical practice. *Psychological Medicine*, 29, 437-446.

Wong, J. G., Clare, I. C. H., Holland, A. J., Watson, P. C. & Gunn, M. (2000). The capacity of people with a 'mental disability' to make a health care decision. *Psychological Medicine*, 30, 295-306.

Training to Give Informed Consent to Medication

Table 1. Questions for each medication type

Medication	Questions
Epilim	<ol style="list-style-type: none"> 1. You have epilepsy. What effect can this have on you? 2. You have epilepsy. Can you tell me what things your doctor has already tried to stop you from having a fit? 3. Your doctor suggested a treatment to help to reduce the number of fits you have. What did he do to help to reduce the fits? 4. The doctor gave you some tablets. Can you tell me some good things AND some bad things that could happen to you if you continue to take the tablets? 5(a). The doctor gave you some tablets to reduce the number of fits. What can you do now? 5(b). What do you think would happen if you said no to taking the tablets? 6. The doctor has suggested you take the tablets. What do you think you should say about taking the tablets now? Why do you think you should say this?
Metformin	<ol style="list-style-type: none"> 1. You have diabetes, which means your blood sugar is high. What effect can this have on you? 2. You have diabetes. Can you tell me what things your doctor has already tried to reduce your blood sugar? 3. Your doctor has suggested a treatment to help to reduce your blood sugar levels. What did he do to help to reduce your blood sugar? 4. The doctor gave you some tablets. Can you tell me some good things AND some bad things that could happen to you if you continue to take the tablets? 5(a). The doctor gave you some tablets to reduce your blood sugar levels. What can you do now? 5(b). What do you think would happen if you said no to taking the tablets? 6. The doctor has suggested you take the tablets. What do you think you should say about taking the tablets now? Why do you think you should say this?
Haloperidol	<ol style="list-style-type: none"> 1. You sometimes feel angry. What has happened in the past when you get angry? 2. You sometimes feel angry. Can you tell me what things your doctor has tried so far to help to control your anger? 3. Your doctor suggested a treatment to help you control your anger. What did he do to help to reduce your anger? 4. The doctor gave you some tablets. Can you tell me some good things AND some bad things that could happen to you if you continue to take the tablets? 5(a). The doctor gave you some tablets to help to control your anger. What can you do now? 5(b). What do you think would happen if you said no to taking the tablets? 6. The doctor has suggested you take the tablets. What do you think you should say about taking the tablets now? Why do you think you should say this?

Training to Give Informed Consent to Medication

Table 2. Mean scores and standard deviations on A-ACQ for each medication at each occasion

A-ACQ mean scores (and standard deviations)

Group	Baseline	First re- assessment	Second re- assessment
Epilepsy (n=16)	4.69 (1.99)	4.81 (1.94)	6.38 (2.19)
Haloperidol (n=5)	4.20 (2.95)	4.40 (2.70)	6.60 (2.88)
Metformin (n=7)	4.71 (1.80)	4.57 (1.72)	7.14 (2.12)

Training to Give Informed Consent to Medication

Table 3. Percentage of participants with various scores on the A-ACQ for all medications pre (baseline) and post training (n=28)

Score	% Pre-training			% Post-training		
	0	1	2	0	1	2
Question						
1	7.14	50	42.86	0	14.29	85.71
2	17.86	60.71	21.43	0	42.86	57.14
3	32.14	64.29	3.57	14.29	67.86	17.85
4	42.86	57.14	0	32.14	60.71	7.15
5a	60.71	39.29	0	35.71	60.71	3.58
5b	60.71	39.29	0	53.57	46.43	0
6	75	25	0	75	25	0