Effectiveness of START psychological intervention in reducing abuse by dementia family carers: randomized controlled trial

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Running title: Carer abusive behavior in dementia: RCT results

Abstract

Background Family carers of people with dementia frequently report acting abusively toward them and carer psychological morbidity predicts this. We explored the longitudinal course of carer abusive behavior over two years. We also investigated whether START (STrAtegies for RelaTives), a psychological intervention which reduces depression and anxiety in family carers also reduces abusive behavior in carers of people living in their own homes.

Methods We included self-identified family carers who gave support at least weekly to people with dementia referred in the previous year to three UK mental health services and a neurological dementia service. We randomly assigned these carers to START, an 8-session, manual-based coping intervention, or treatment as usual (TAU). Carer abusive behavior (Modified Conflict Tactic Scale (MCTS) score $\geqslant 2$ representing significant abuse) was assessed at baseline, 4, 8, 12 and 24 months.

Results We recruited 260 carers, 173 to START and 87 to TAU. There was no evidence that abusive behavior levels differed between randomization groups or changed over time. A quarter of carers still reported significant abuse after two years, but those not acting abusively at baseline did not become abusive.

Conclusion There was no evidence that START, which reduced carer anxiety and depression, reduced carer abusive behavior. For ethical reasons we frequently intervened to manage concerning abuse reported in both groups, which may have disguised an intervention effect. Future dementia research should include elder abuse as an outcome, and consider carefully how to manage detected abuse.

Trial registration: ISCTRN70017938

Key words

Dementia, Carers, RCT, elder abuse

Introduction

Preventing elder abuse is a political priority (House of Commons Health Committee, 2004). It predicts institutionalization and hospitalization (Dong and Simon, 2013;Dong *et al.*, 2013). People with dementia are particularly vulnerable and frequently abused (Cooper *et al.*, 2008b). In recent studies a third of family carers reported acting in a way that met definitions of significant psychological or physical abuse (Cooper *et al.*, 2008b;Cooper *et al.*, 2009), although they are often unaware their behaviors would be thus defined. In two longitudinal studies, abusive behavior reported by dementia family carers increased over a year, and was predicted by anxiety and depressive symptoms (Cooper *et al.*, 2010a;Rush Smith *et al.*, 2005;Cooper *et al.*, 2010a).

As people with dementia are most often abused and this is most frequently by their carer, they are a very important group to target. A recent non-randomized study found that intervening with professional carers reduced abusive behavior (Hsieh *et al.*, 2009), but no interventions are known to reduce abuse by family carers (Ploeg *et al.*, 2009).

The START (STrAtegies for RelaTives) study, a randomized controlled trial (RCT) of a manualized psychological intervention for dementia family carers reduced carer anxiety and depression (Livingston *et al.*, 2013;Knapp *et al.*, 2013;Livingston *et al.*, 2014a;Livingston *et al.*, 2014b) We have previously reported that abusive behavior reported did not differ between carers in intervention and control groups in the whole trial population (Livingston *et al.*, 2014a). This original analysis, however, did not exclude family carers for people who moved to care homes during the trial, after which point the family carers were unlikely to report abusive behavior as they were no longer providing day to day care. This paper is the first to report levels of abuse over two years, and also the first analysis of an RCT with the outcome of abuse towards people with dementia while they were living in their own homes. We tested our hypothesis that the START intervention reduced reported abusive behavior towards people with dementia living at home, compared with Treatment as Usual (TAU) alone.

Methods

Study design

START was a parallel-group, powered to show the intervention was superior to TAU on the primary outcome, single-blind, randomized controlled trial, recruiting participants 2:1 to intervention: treatment as usual (TAU) to allow for therapist clustering, at four UK sites. Methods are described in detail elsewhere (Knapp *et al.*, 2013;Livingston *et al.*, 2013). This trial is registered: ISCTRN 70017938.

Participants and setting

Inclusion criteria: Eligible participants were self-identified family carers providing support at least weekly to people with a clinical dementia diagnosis, living in their own homes. The patients had been referred to the clinical team in the previous year. Exclusion criteria: Carers who were unable to give informed consent to the trial, or who were already in a trial of carer support or lived over 1.5 hours from the researchers' base. We recruited from 04/11/2009 to 08/06/2011 from three mental health trusts and a tertiary neurology clinic in South East England. We obtained written ethics approval for the study from East London and the City Research Ethics Committee 1 for the trial (ID: 09\H0703\84) and Research and Development permission from the local trusts. All participants gave written informed consent.

Procedures

Randomization was stratified by centre using random permuted blocks via an online computer-generated randomization system from an independent Clinical Trials Unit. Assessors were blinded to randomization status, but study participants knew their allocation. We developed the eight-session START manual-based individual coping intervention for dementia family carers from the American "Coping with Caregiving" programme (Gallagher-Thompson *et al.*, 2002). We trained and supervised non-clinically trained psychology graduates to deliver it. We devised a fidelity checklist for each session by considering the most important components of the session and then scored the session fidelity from 1, 'not at all', to 5, 'very' focused. This was completed from an audio-recording by a therapist who did not deliver the intervention. Therapists recorded one therapy session per participant selected at random by the trial manager. Sessions were usually in participants' homes, unless they preferred the team's office. The graduate therapists were encouraged to be empathic, adhere to the manual, and work collaboratively with carers rather than giving solutions or advice. Therapists and carers identified difficulties and implemented strategies to manage them, including: relaxation, behavioral management, communication strategies, identifying and changing unhelpful thoughts, positive reframing, accessing emotional support, future planning and increasing pleasant events. The carers were asked to practise the manual and relaxation CDs between sessions. In the final session, carers and therapists developed a maintenance plan of useful strategies. There are more details of the treatment in the full report (Livingston *et al.*, 2014a). Although carers are given information about dementia and told about services, none of the other features of the intervention are part of treatment as usual, nor is the information given necessarily systematic.

TAU within the trusts involved in the trial was based on NICE guidelines(National Institute for Clinical Excellence and Social Care Institute for Excellence (NICE/SCIE), 2006). TAU consisted of assessment, diagnosis and information-giving, risk assessment and management, drug treatment, cognitive stimulation therapy, practical support, and treatment of neuropsychiatric and cognitive symptoms.

Outcomes

The full assessment methods have been reported elsewhere (Livingston *et al.*, 2013). Carers were interviewed at baseline, short term (4 and 8 month) and long term (12 and 24 month) after randomization. They completed the Modified Conflict Tactics Scale (MCTS) each time. This is a self-completed measure of potentially abusive behavior by carers towards the care recipient which has been validated and used previously with family carers of people with dementia(Beach et al., 2005; Cooper *et al.*, 2008a). Ten behaviors ranging from shouting, to threatening to shaking or slapping, are scored as to whether, during the previous 3 months, they occurred never (0), almost never (1), sometimes (2), most of the time (3) or all of the time (4) and item-scores are summed. Where participants scored ≥2 on any item, this is classified as significant abuse, so the researcher discussed the behavior with a supervising clinician. If concerns were raised, a plan was made with one of the lead investigators about how to manage the risk. If it was judged that the person with dementia was at risk, permission was asked and given to inform the clinical team so that the carer and patient could have appropriate help. No one was lost to the study as a result of this process.

Statistical analysis

The study was powered for the primary outcome, carer mood. Participant allocation was unequal to allow for therapist clustering in the intervention arm. MCTS was a secondary outcome and our analyses were exploratory but predetermined and signalled in the main report (Livingston *et al.*, 2014a). We describe the numbers and percentage of those engaging in possibly abusive behavior by allocation group and time. Analyses were intention to treat. We censored data at the assessment before any care home admission, as care home staff would then be providing personal and day to day care. We explored MCTS score differences between groups (binary outcomes and continuous). We used random effects models allowing for repeated measures adjusted for baseline MCTS, centre, time, group, patient age and sex to consider differences in potentially abusive behavior between randomised groups on binary outcomes only as the continuous data were very skewed. We used sensitivity models which also adjusted for baseline imbalances (carer work, carer education, patient education, relationship with carer, lives with carer) and which showed very similar results. Additionally, sensitivity models adjusting for these and baseline demographic/clinical predictors of missing showed similar results.

Results

260/450 (58%) eligible carers consented. The remainder refused to participate or were uncontactable. The known personal details of those who consented and those who did not were compared and shows that the study sample had good external validity (Livingston *et al.*, 2013) 173 (66.5%) participants were randomized to the intervention group and 87 to TAU. Data from 213 (82%) of carers recruited were included in our analyses and 173 (67%) remained in the study for two years. 17 TAU group and 32 intervention group carer recipients were admitted to care homes over the study and their data were censored (see Figure 1 for consort diagram). Baseline characteristics are shown in Table 1. Table 2 describes the numbers and percentage of those engaging in possibly abusive behavior by allocation group and time.

There was no significant difference in the proportion with MCTS score $\geqslant 2$ (figure 3) between randomization groups over two years in regression models, controlling for baseline MCTS score, centre and time (n=213, Odds Ratio (OR) 0.59, 95% Confidence Interval (CI) 0.27-1.28, p=0.18), or when differentiating between short and long term follow-ups (n=213, OR 0.54, 95% CI 0.23-1.28 p=0.16 and OR 0.67, 95% CI 0.25-1.80, p=0.43 respectively); or after additionally controlling for patient age and gender (n=213, (OR 0.65, 95% CI 0.31-1.36, p=0.25).

Figure 2 and 3 show the median MCTS score and the percentage reporting significant abuse over time. Among participants who reported some abuse at baseline, median abuse scores decreased over the two years by two MCTS score points in both control and intervention groups. There were also very similar decreases in the proportions reporting significant abuse in the two groups. When we compared the final model with the same model but excluding time, the change in “fit” of the model was not significant (p=0.46).

Discussion

This is the first RCT with abusive behavior towards people with dementia as an outcome. Nearly half of the participants reported significantly abusive behavior at baseline and the START intervention did not decrease this compared to TAU. The parallel decrease in median abuse scores suggest that the lack of effect was not due to lack of power but was a true finding.

Carers who are anxious or depressed report more abusive behavior towards care recipients (Cooper *et al.*, 2010a;Rush Smith *et al.*, 2005). In two previous naturalistic longitudinal studies caregiver-reported abusive behaviors increased over a year (Cooper *et al.*, 2010a;Smith *et al.*, 2011). Carers in the first group were identified through National Health Service secondary care providers in the United Kingdom and therefore would be expected to be recipients of treatment as usual. Those in the second group were found from more disparate sources and only some will have received health care. Given that abusive behavior has been associated with neuropsychiatric symptoms(Cooper *et al.*, 2010b), which increase with dementia severity, it is perhaps surprising that abusive behavior did not similarly increase in this, the longest prospective study of dementia carer abusive behavior to date. We intervened when the carer was acting in a significantly abusive way. Our intervention was to discuss with the carer how this behavior was problematic and probably indicated that they needed more support. We would then tell the clinical teams of the problem and they decided how to proceed. They did not release clinical details of their actions to the research team. The discussion about the abusive behavior and the need for support might explain why abuse did not increase, as the threshold for intervening was probably lower than in the previous studies. Potentially, where it did not, it may have dissuaded carers who were still acting abusively from reporting this again. Alternatively naming behaviors as abusive through completing the baseline measure might have led some carers to seek solutions to difficulties provoking these behaviors.

This is the first study to consider outcomes for carers based on whether they reported behaving abusively at baseline. A quarter of carers still reported significant abuse after two years, but those not acting abusively at baseline did not become abusive. START decreased anxiety and depression and increased quality of life in family carers. We thus uncoupled the abusive behavior and carer anxiety and depression. An effective evidence based intervention to reduce abuse is urgently needed and should target carers reporting abusive behavior as a priority rather than as a preventative intervention. Follow-up compared favourably with other longitudinal studies and our models allowed analyses of 82% of study participants, but data was missing for a third of carers by 24 months, and those who withdrew from the study might have been more or less likely to be acting abusively.

Our findings that abusive behavior reported by carers in our study did not, as in previous longitudinal studies, increase over time suggest that talking about abusive behavior and offering support may help carers accept rather than act on negative feelings within caring relationships. Additionally, a future abuse prevention intervention might usefully focus on encouraging professionals to talk about abusive behavior and offer support to reduce abusive behavior to those who report it. Our study highlights the challenges of designing an RCT with abuse as an outcome, as there may be an ethical need to intervene to try to reduce abuse reported in the control group.

Conflict of interest

None

Description of authors' roles

All authors developed the analysis plan and MG carried out the analyses; CC drafted the paper and all authors revised it for important intellectual content and agreed the final version. GL was chief investigator of the START trial.

Acknowledgements

With thanks to the National Institute for Health Research HTA programme for funding the START trial (08/14/06).

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Figure 1 Consort diagram

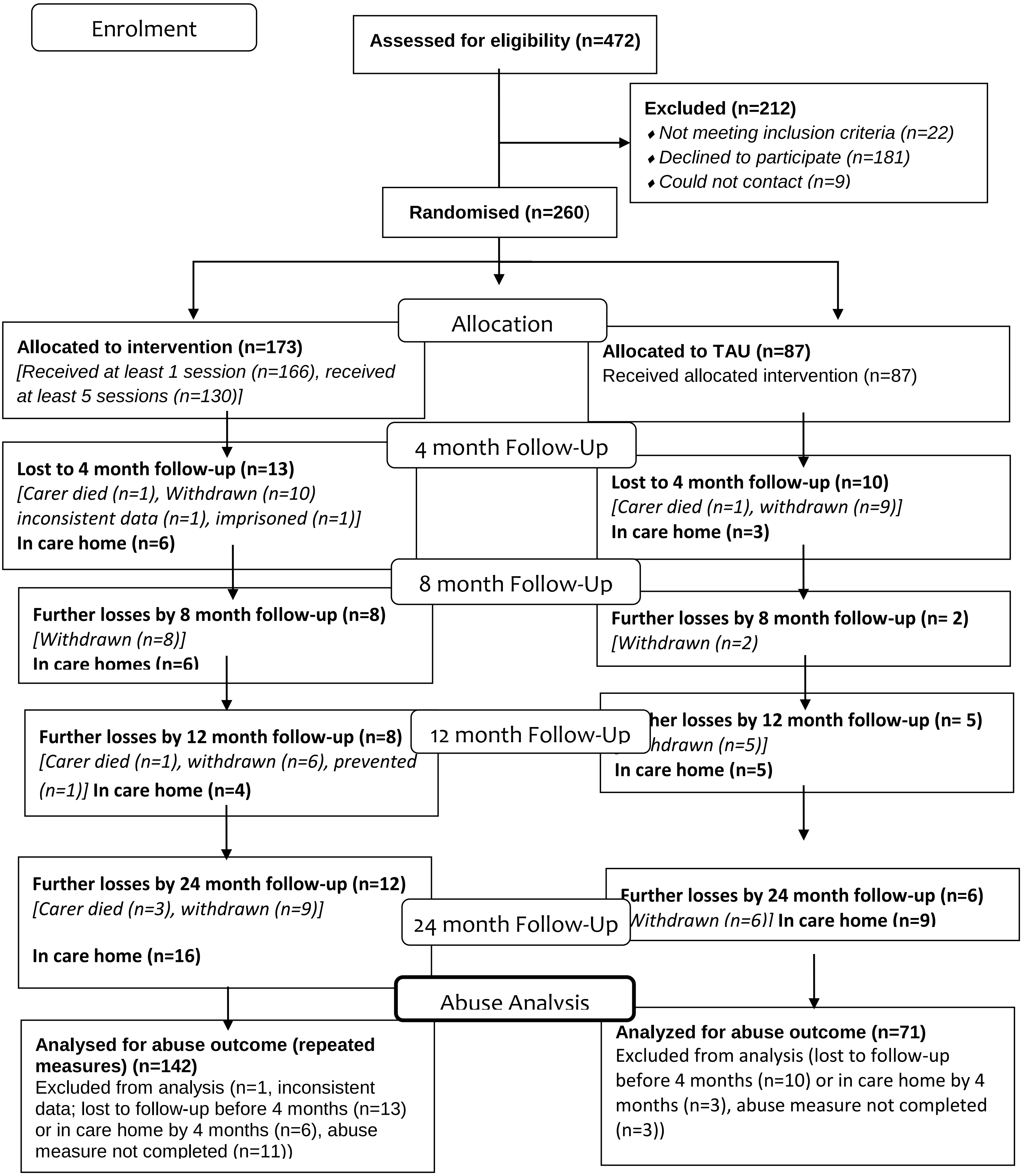

Figure 2: Median MCTS total score at each follow-up by group and whether any abuse was reported at baseline

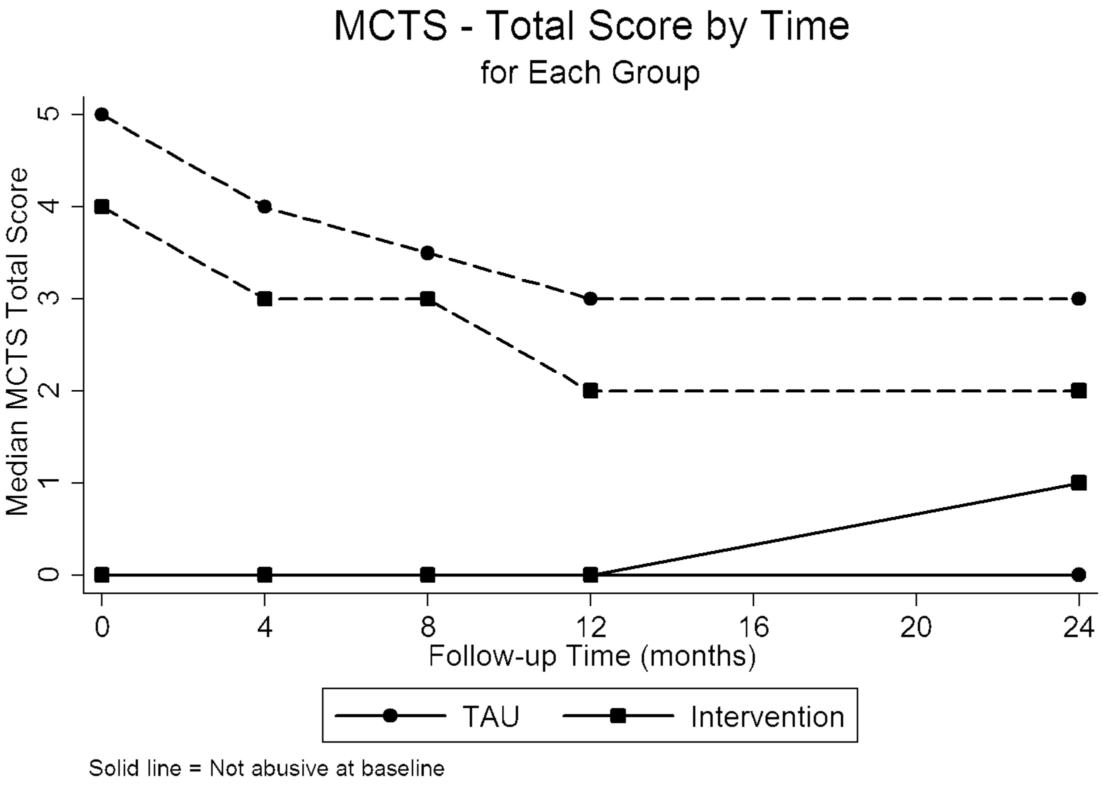

Figure 3: Modified Conflict Tactic Scale (MCTS) significant abuse (≥2) at baseline and each follow-up and whether any abuse was reported by group

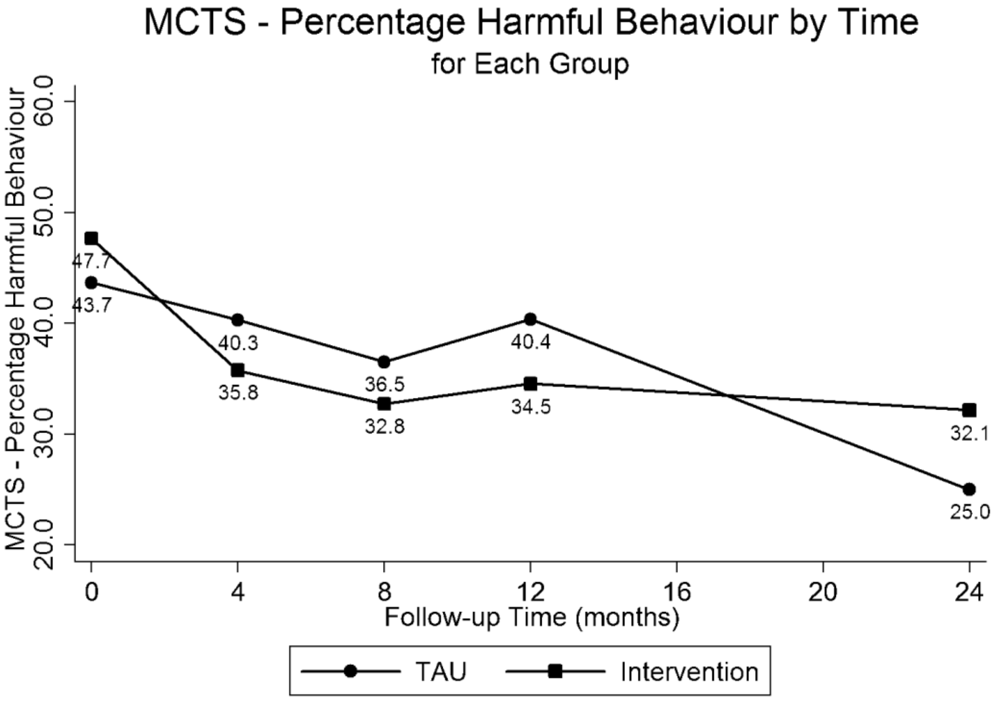

Table 1 Demographic characteristics and abuse score of sample

	Carer		Patient	
	TAU	**Intervention**	**TAU**	**Intervention**
Demographic	**Mean (SD)**		**Mean (SD)**	
Age				
Years	56.1 (12.3) (n=87)	62.0 (14.6) (n=172)	78.0 (9.9) (n=87)	79.9 (8.3) (n=173)
	Number (%)		**Number (%)**	
Gender				
Female	62 (71.3%)	116 (67.1%)	50 (57.5%)	102 (59.0%)
Male	25 (28.7%)	57 (32.9%)	37 (42.5%)	71 (41.0%)
Total	87	173	87	173
Living With Carer				
Yes	n/a	n/a	50 (57.5%)	113 (65.3%)
Total	n/a	n/a	87	173
MCTS Total				
	2.7 (3.1) (n=87)	2.5 (2.9) (n=172)	n/a	n/a

Table 2 MCTS harmful behavior (at least one item >=2)

	Baseline		**Four months**		**Eight months**		**Twelve months**		**Twenty-four months**	
	TAU	**Intervention**	**TAU**	**Intervention**	**TAU**	**Intervention**	**TAU**	**Intervention**	**TAU**	**Interve**
No (%)	42 (60.0)	70 (50.4)	33 (58.9)	76 (65.5)	34 (65.4)	71 (71.7)	27 (58.7)	64 (66.0)	30 (75.0)	57 (67.9)
Yes (%)	28 (40.0)	69 (49.6)	23 (41.1)	40 (34.5)	18 (34.6)	28 (28.3)	19 (41.3)	33 (34.0)	10 (25.0)	27 (32.1)
Total	70	139	56	116	52	99	46	97	40	84