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Does allocation to a control condition in a Randomized Controlled Trial affect the routine care foster parents receive?

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ABSTRACT

'Strengthening Foster parents in Parenting' (SFP) is a support program for foster parents who care for foster children with externalizing problem behavior. Its effectiveness was examined with a Randomized Controlled Trial (RCT). In this paper, we examine the treatment as usual (TAU) that was offered in the control condition of this RCT. For this purpose, the TAU from the SFP control group was compared with TAU provided to a similar group of foster parents outside any RCT.

Our results show that TAU is diverse and varies widely. Furthermore, being part of the control condition was positively associated with both the counseling frequency from the foster care services and with external help-seeking behavior (finding and using additional support).

In order to prevent condition contamination in future trials, TAU should be clearly described and standardized, and treatment fidelity should be carefully monitored.

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1. Introduction

> "*Sound scientific clinical investigation almost always demands that a control group be used against which the new intervention can be compared*".
>
> [Friedman, 1998 in Minneci et al. (2008, p. 942)]

A Randomized Controlled Trial (RCT) study design is considered the gold standard for evaluating the efficacy of an intervention (Nezu & Nezu, 2008). Control conditions may, however, have a substantial impact on the results of RCTs (Mohr et al., 2009). They are roughly divided into three groups, namely: control conditions with treatment that is defined and controlled by the researcher, control conditions with treatment that is not defined by the researcher, and control conditions without treatment (Mohr et al., 2009). The care already offered in the context of the research and the population from which participants are recruited, determine the type of control condition (Freedland, Mohr, Davidson, & Schwartz, 2011). Moreover, people enrolled in control conditions usually have access to external assistance. Freedland et al. (2011) talk about 'non-study care' that is present in almost all control groups, but which is often overlooked when research designs are described. Since the results of an RCT depend as much on the selected control condition as on the experimental intervention (Mohr et al., 2009), it is important to pay close attention to the care and support offered in a control condition. This is especially true if treatment as usual (TAU) is offered, in literature also referred to as 'care as usual' or 'routine care'. TAU refers to the usual care and support a study population would receive if not assigned to a randomized study design. However, TAU is highly vulnerable to unintended intensification (Freedland et al., 2011) due to the awareness of participants that they are taking part in a research design, being monitored and evaluated, and not immediately receiving 'potentially better care' that is offered to the experimental group.

In this exploratory study, we describe the support offered to foster families who were assigned to a control condition of an RCT study design and we examine whether it is representative of the routine care for foster families. More specifically, we examine whether assignment to the control condition had an effect on the TAU these foster families received. First, we briefly discuss the research design, and then go into the characteristics of routine care in the Flemish foster care context. Subsequently we formulate the research question. Finally the research results are reported and discussed.

2. Strengthening Foster parents in Parenting

Between 2009 and 2014, the Flemish government (i.e., the Dutch speaking part of Belgium) subsidized a specific foster parent intervention called 'Strengthening Foster parents in Parenting' (SFP), offered as a foster care service in addition to regular casework. SFP offers two

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training programs based on different theoretical models to foster parents of children aged three to eighteen years with externalizing behavioral problems (Vanschoonlandt, Van Holen, & Vanderfaeillie, 2012). The first training program is based on the social interactional model and targets foster parents of children aged between three and twelve years (Vanschoonlandt, Vanderfaeillie, & Van Holen, 2012). The second is based on nonviolent resistance and targets foster parents of children aged between six and eighteen years (Van Holen, Vanderfaeillie, & Omer, submitted for publication). Both protocolled interventions consist of ten, weekly, individual sessions during which foster parents learn how to deal with externalizing behavioral problems of their foster child. The average duration of the intervention is 3.5 months. SFP was evaluated in an RCT with 125 participating foster parents. In order to enroll participants, all new long-term family foster placements in sixteen out of seventeen Flemish foster care agencies were compulsorily screened during four months after the start of the placement. Part of the screening consisted of completing the Child Behavior Checklist (CBCL1.5–6/6–18; Achenbach & Rescorla, 2000, 2001) by foster mothers and a questionnaire filled in by the regular foster care worker that, inter alia, assessed the presence of exclusion criteria (foster child has a mental retardation or autism or uses psychotropic medication in an inconsistent way, behavioral problems are the result of medical problems or medication, foster parents have a mental/psychological disability, and foster parents are involved in a divorce.). Besides new foster placements, foster care workers could also sign up ongoing long-term placements. In these situations, the same questionnaires were filled in to evaluate whether foster parents were eligible for enrolment. Foster parents were eligible to participate in the SFP program if, taking into account the exclusion criteria, the foster child had a borderline or clinical score on one of the small-band externalizing scales or the broad-band externalizing scale of the Child Behavior Checklist. Foster care workers of eligible foster parents were informed and asked to motivate their foster parents to participate in the SFP program. Once foster parents agreed to participate, they were allocated at random to the intervention or control group. The intervention group was offered the training immediately. Control families received TAU and were offered the training after the data collection for the RCT was completed (i.e., seven months after enrolment).

3. TAU in Flemish foster care

Seventeen foster care agencies, spread across Flanders, are subsidized by the Youth Welfare Agency. By law, these agencies are responsible for the selection and pre-service training of foster parents, ongoing support for foster parents and monitoring of the foster care placement (Besluit van de Vlaamse regering inzake de erkenningsvoorwaarden en de subsidienormen voor de voorzieningen van de bijzondere jeugdbijstand, 1994). As a result, foster families that are assigned to a control condition of an RCT, regardless of any ethical concerns, are entitled to receive TAU. Foster care workers organize support for the foster child, optimize contacts with birth parents and family, and coach and train foster parents (Verreth, 2009). More specifically, the support for foster care situations comprises of at least seven face-to-face contacts a year (Sprangers, 2009). However, it is not defined with whom these contacts should take place. They can be with foster parents, foster children, birth parents, the wider context of the foster child (e.g., grandparents) and combinations of the parties involved (e.g., foster parents and foster child together). Furthermore, certain aspects of good practice (e.g., the use of care plans) are obligatory (www.pleegzorgvlaanderen.be). Although foster care workers have considerable autonomy within these guidelines, a caseload of 25 foster care placements for a full-time foster care worker (Vanschoonlandt, Vanderfaeillie, Van Holen, De Maeyer, & Robberechts, 2013) hinders them from providing intensive support to foster parents. Bronselaer, Vandezande, and Verreth (2011), for example, found that the majority of foster parents (56%) only had a few contacts (face-to-face or by telephone) a year with their foster care worker, 32% monthly, 7% fortnightly and 3% weekly. A very small percentage reported having no contact with their foster care worker at all (1%) or only once a year (2%). Herewith, nothing is said about the content of these contacts or about the practices used by the foster care worker. As well as individual counseling, foster care agencies also offer on average four collective (non-mandatory) group training sessions a year (Bronselaer et al., 2011). However, Bronselaer et al. (2011) found that 77.7% of foster parents had not attended any group training during the past five years. With regard to the counseling offered to birth parents, no such data are available in Flanders.

In addition to the regular foster care support described above, foster parents have access to external mental health care services for themselves or for their foster child. Internationally, the frequency rate of using external services varies widely due to differences in the definition of mental health care, in the research period, in the study population (i.e., age of the foster children and the time they spent in care) and in policy. The use of mental health services for foster children in the U.S. ranges from 26% (Bellamy, Gopalan, & Traube, 2010) to 56% (Garland, Landsverk, Hough, & Ellis-MacLeod, 1996). In a national survey in the U.S. of foster children who were placed for twelve months, Leslie, Hurlburt, Landsverk, Barth, and Slymen (2004) found that 75.8% of the children with a clinical score on at least one of the broad-band scales of the CBCL received mental health care. In an Australian study, 26.9% of the foster children aged between six and seventeen years received professional help, while 53.4% of the foster parents reported that their foster child needed additional professional help (Sawyer, Carbone, Searle, & Robinson, 2007). Another Australian study reported that 44% of foster children aged between four and nine years received individual therapy (Tarren-Sweeney, 2010). Minnis, Everett, Pelosi, Dunn, and Knapp (2006) found that 18% of Scottish foster children aged between five and sixteen years consulted a child psychologist or psychiatrist. A Flemish study of 212 new long-term foster care placements of children aged three to eighteen years showed that respectively for 17.5% of the foster children and for 9.1% of the foster parents, additional help was offered or planned (Vanschoonlandt et al., 2013). However, only 20.9% of the foster children with severe externalizing problems (measured by the CBCL) and 13.9% of the foster parents who took care of those children received extra help. In a larger Flemish study including all ages and kinds of foster care, Bronselaer et al. (2011) reported that 32% of foster carers made use of parenting support services during the last twelve months and 25% of mental health services.

In short, the above shows that the help offered during a foster care placement is very diverse and heterogeneous and that the support for foster families varies enormously. It is not unthinkable that the TAU received by foster families in a control group differs considerably between participants. Nevertheless, even in such control groups it is common to talk about TAU, although such a label seems to oversimplify the conditions to which the participants are exposed (Freedland et al., 2011).

4. Research question

In this study, we described the support for foster parents who were assigned to a control condition in an RCT study design and compared it with the support received by a similar group of foster parents who did not participate in an RCT. The research question was: “Does assignment to a control group in an RCT affect the TAU for foster parents?”

5. Method

5.1. Participants

The SFP control group consisted of 64 foster families with a foster child aged between three and eighteen years with a borderline or clinical score on the broad-band externalizing scale or on one of the

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