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2 Evaluation of an Intervention Program for Families with Children at Risk for

3 Maltreatment and Developmental Impairment: A Preliminary Study

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Abstract

This study evaluated the preliminary effects of an early intervention program for parents and children at-risk. In this study, a sample of 40 children were randomly assigned to a 9-months intervention program (intervention group, $n = 20$) or remained in usual practice conditions (control group, $n = 20$). The intervention involved group dynamics with children in pre-school and individual work sessions with the parents and the children at home. A repeated measures design 2x2 was used to test the program effects on parenting practices (Maltreatment Questionnaire) and on children's mental and social development (Griffiths Mental Development Scales). Results revealed that the program had a positive impact mostly on parenting practices, decreasing physical and psychological abuse ($d = -1.01$), physical neglect ($d = -0.71$) and lack of supervision ($d = -0.48$), but also on measures of cognitive development (i.e., hearing and language; $d = 0.31$). The program reinforces the importance and effectiveness of attunement intervention programs for parents and for children.

Keywords: Early Intervention Program; Parents and Children; Program Evaluation

Introduction

1
2 There is a comprehensive literature on the risk factors for abuse and neglect, and four
3 major domains of risk have been identified (Belsky, 1993; Jennifer, Duffy, Hughes, Asnesa,
4 & Leventhal, 2014; Sidebotham & Heron, 2006): child characteristics (e.g., disability, few
5 positive attributes reported); parental characteristics (e.g., absent father; single mother);
6 family characteristics (e.g., poverty; low educational achievement; domestic violence); and
7 social characteristics (e.g., violent neighborhoods; social deprivation; and poor social
8 network). Evidence also indicates that children with more risk factors are more likely to have
9 experienced maltreatment compared to those with no risk factors (e.g., Brown, Cohen,
10 Johnson, & Salzinger, 1998). Furthermore, children from disadvantaged and socially
11 challenged backgrounds are also more likely to have cognitive development difficulties,
12 behavioral problems, learning difficulties and social problems in general. Exposure to early
13 stress has deleterious effects on the development of the children's regulatory systems, leading
14 to increased problematic behavior with corresponding long-term implications for
15 psychological and health vulnerabilities (e.g., Anderson et al., 2003; Phillips & Shonkoff,
16 2000). Evidence also shows that these effects tend to endure in these populations, meaning
17 that these children, as adults, tend to have greater difficulties with psychosocial integration
18 and more health problems (e.g., Poulton et al., 2002; Roosa, Jones, Tein, & Cree, 2003).
19 Importantly, the exercise of the parenting role is considered a proximal feature in
20 understanding the negative associations between family, social and economic disadvantages
21 and children's development (Belsky, 1993; Dodge & Pettit, 2003). Parental risk factors for
22 child maltreatment include low socio-economic status, single parenthood, exposure to
23 relational violence, and multiple indices of social deprivation, sometimes leading to the
24 involvement of social work services and/or child protection measures (e.g., Stith, Liu, Davies,
25 Boykin, Alder, Harris, et al. 2009).

1 Portugal is a country still struggling with problems of poverty and maltreatment.
2 Children up to age 5 constituted 19.6% (14.110) of all referrals to Child and Youth Protection
3 Committees (CPCJ) (Comissão Nacional de Proteção das Crianças e Jovens em Risco
4 [CNPCJR], 2015). The committees found these younger children in conditions of
5 psychological maltreatment (19.7%) and physical maltreatment (19.6%); and with more
6 domestic violence (44.4%) and neglect (35.8%) comparing with all CPCJ children in 2015
7 (CNPCJR, 2015). Furthermore, in Portugal one fifth of the children live below the poverty
8 line (Bastos & Nunes, 2009), and the number of children with 5 years or younger that are
9 exposed to risk factors and reported to Child Protection System has been increasing (24.5% of
10 all new reports, N= 7.267; CPCJR, 2015). Thus, it is critical to design and evaluate
11 interventions to help prevent or minimize these problems, but the child protection system in
12 Portugal is still characterized by a lack of specific and differentiated responses, and a need of
13 qualified and extended social services to support and improve parenting (Instituto da
14 Segurança Social, 2017; Rodrigues, Barbosa-Ducharme, & del Valle, 2013). Furthermore, the
15 lack of investment on a family-focused system is reflected in a disproportionate number of
16 children and youth in residential care in the Portuguese context (Instituto da Segurança Social,
17 2017) compared with other countries in most Western societies (Del Valle & Bravo, 2013),
18 and contrary to the international recommendations about out-of-home placements, particularly
19 for young children (Browne, 2009).

20 Interventions to address the needs of children from disadvantaged socio-economic
21 backgrounds and environments at-risk for maltreatment require a specific definition of their
22 target and scope, their approach, and provide evidence on their effectiveness and evaluation
23 criteria. In terms of target and scope, there have been calls for interventions which focus both
24 on the child and the family (Department of Health, 2000; Letarte, Normandeau, & Allard,
25 2010; Macbeth, Law, McGowan, Norrie, Thompson, & Wilson, 2015), with a systemic or

1 ecological approach. When children are identified as being at risk, it is essential to create a
2 diagnosis and intervention plan which focuses not only on the developmental needs of the
3 child, but also on parenting skills along with other environmental factors (Department of
4 Health, 2000). However, intervention programs which are evaluated through experimental or
5 quasi-experimental designs usually do not deliver interventions with a multitude of risk
6 factors at the level of children and parents (complex interventions, i.e., focused on different
7 sub-systems that mutually influence each other; Charles, Bywater, & Edwards, 2011;
8 Macbeth, Law, McGowan, Norrie, Thompson, & Wilson, 2015) or assess results at different
9 levels of child functioning and/or family (Casanueva, Martin, Runyan, Barth, & Bradley,
10 2008; Letarte, Normandeau, & Allard, 2010). Furthermore, the evaluation of the effectiveness
11 of early intervention in childhood has focused primarily on the intellectual functioning of
12 children (Anderson et al., 2003), and few interventions using randomized controlled designs
13 with general or at-risk populations were evaluated also in terms of their impact on practices of
14 parental maltreatment (Dagenais, Bégin, Bouchard, & Fortin, 2004; Letarte, Normandeau, &
15 Allard, 2010). It is also important to implement and continually evaluate these interventions
16 with target-groups in contexts with different historical, cultural and social backgrounds
17 (Moran, Ghate, & Van der Merwe, 2004).

18 This article describes an intervention program which sought to address these issues.
19 Drawing on a previous needs assessment (see Calheiros et al., 2014), as well as
20 recommendations regarding the development of programs that are comprehensive regarding
21 the parents' and children's needs (Charles, Bywater, & Edwards, 2011; Dretzke, et al., 2009;
22 Schensul, 2009; Whittaker & Cowley, 2012), the main goals are: (1) to design an attunement
23 early intervention program for families with children at risk for maltreatment and
24 developmental impairment, in a pre-school setting in Portugal (Family Support Program -
25 FSP); 2) to improve the parenting practices, and the cognitive, social, and personal

1 development of children; and 3) to evaluate the program using experimental methods,
2 responding to the limitations pointed in terms of design and variable types, namely the
3 parenting practices regarding abuse and neglect and different dimensions of child-
4 development. This article provides a description of a further set of findings from the project
5 and evaluation firstly presented in Calheiros et al. (2014). However, there are no duplicate or
6 overlapped data – all findings reported in each article are original and complement each other.

7

8

Method

9 Participants

10 Sixty-nine families with children were initially enrolled in the randomized-controlled
11 trial designed to test the program. Families and children were recruited from the community
12 children center in Lisbon (Portugal), in which the needs assessment (Calheiros et al., 2014)
13 was undertaken. Families were selected for inclusion to the study on the basis of two sets of
14 criteria.

15 First, parents were approached personally to consent to participate if they: (a) had at
16 least one child in pre-school; (b) children between three and five years old; and (c) families
17 planning to keep their child in the pre-school during the next school year. Sixty-three families
18 were in conditions to participate in the study. Where written consent was obtained, a second
19 inclusion criteria set was used for selection to the study. Based on the needs assessment
20 (Calheiros et al., 2014), participants were selected through inclusion (i.e. the families were
21 included if they meet at least one of these inclusion criterion: young children showing signs of
22 social behavioral problems, difficulties in social, emotional and cognitive development and/or
23 belonging to families lacking parenting skills) and exclusion (e.g., severe negligence or
24 evidence of ill-treatment, physical health problems in both responsible adults, severe
25 psychological problems of one of the parents, drug or alcohol abuse, criminal behavior, and/or

1 children with severe psychological problems) criteria. These criteria were obtained by the
2 same practice tool (Aggregating Data; Little, Axford, & Morpeth, 2002) that was used to
3 gather indicators on the child and respective family in the needs assessment. Information for
4 each case was collected jointly by three professionals (educator, social worker and
5 psychologist) working with the children directly. Following this procedure, 40 children and
6 their parents were selected and randomly assigned. The professionals randomly attributed a
7 number to each child from 1 to 40, and the research team sorted the children into two groups
8 (even numbers vs. uneven numbers). The children were then assigned either to the
9 intervention group ($n = 20$) or control group ($n = 20$), and were evaluated before (T1) and
10 after implementation of the program (T2). Four families dropped out of the project due to a
11 change of address, one of the intervention group and three of the control group. Thus, the
12 analysis of the data includes 36 families, 19 in the intervention group and 17 in the group
13 without intervention. To address the attrition in the sample t-tests were conducted. This
14 analysis indicated that those who dropped-out and those who did not, do not differ on their
15 initial evaluation.

16 The children were between three and five years old ($M = 4.26$, $SD = 0.715$), 55% were
17 female, 61.5% were Caucasian, 35.9% were African and the rest of mixed ethnicity.

18 The mothers were on average 33.05 years old ($SD = 5.89$), 43.6% had a sixth-grade
19 education, and 33.3% were unemployed. The fathers were on average 36.53 years old ($SD =$
20 8.60), 52.9% had a sixth-grade education, and 22.6% were unemployed. Analysis of variance
21 and Chi-square for comparison of the characteristics of the two groups showed no significant
22 differences in terms of ethnicity, family composition, educational levels of parents and work
23 status.

24

25 **Procedures**

1 Families voluntarily participated in the program, which lasted nine months. The
2 families were informed of the objectives and content of the program and signed an informed
3 consent before participating. In the first sessions, a pre intervention assessment (T1) was
4 conducted with the intervention and control group. All children received usual preschool
5 services, i.e., educational activity in a kindergarten open for more than 5 hours a day, 5 days a
6 week, in a group size of 25 children and with a child-staff ratio of 25:2; the classroom is the
7 organizational unit and each class has a qualified pre-school teacher assisted by a non-
8 qualified auxiliary member of staff (Law No. 5/97). In addition, the intervention group
9 participated in the Family Support Program while the comparison group received only the
10 usual pre-school services. A post intervention assessment (T2) was conducted at the end of
11 the implementation of the program. Confidentiality and anonymity were insured in both
12 evaluations.

13 Design and implementation of the program - The Family Support Program was
14 tailored using the procedures proposed in the ADAPT-ITT model (Storer, Barkan, Sherman,
15 Haggerty, & Mattos, 2012), which offers a set of steps for adapting evidence-based programs
16 in social and educational service settings, and focuses on collaboration and consultation with
17 key stakeholders from clients to frontline staff. In particular, following the needs assessment,
18 the definition of the theoretical model, and the design of a general logic model of the
19 intervention, seven steps were followed: (1) assessment using focus groups with parents, (2)
20 decisions on program augmentations and improvement from focus groups, (3) production of
21 new program content, (4) review the content by professionals and academics, (5) integration
22 into the program, (6) training the new material to implementers, and (7) testing and
23 evaluation. To promote the involvement of parents, the program also focused on the family's
24 requests (Nelson, Lord, & Ochocka, 2001; Storer, Barkan, Sherman, Haggerty, & Mattos,

1 2012), defining shared objectives in accordance with their priorities and their perception of
2 the problems.

3 The Family Support Program is a multi-component program that takes on a holistic
4 perspective in encouraging the proper functioning of the parents, developed at a socio-
5 educational institution for children in a vulnerable social/family situation (Calheiros et al.,
6 2014). It follows the principles of cognitive and behavioral parents interventions, based on
7 social learning models (Taylor & Biglan, 1998). Thus, the intervention, based on the
8 Comprehensive Child Development Program (CCDP) (Pierre, Layzer, Goodson, & Bernstein,
9 1997) was organized in two specific intervention components: one at parent level - Parental
10 Relations – and the other at the level of child - Development of the Personal, Social and
11 Cognitive Skills of the Child.

12 The intervention unit created a multidisciplinary team who provided the necessary
13 interventions with each family and child. The multidisciplinary intervention team comprised
14 one coordinator, one social worker, one psychologist, one childhood educator and two social
15 educators, all working part-time. Case managers (social worker or a psychologist) and
16 professionals for each family (the maximum three per family) were team members chosen
17 based on the central problem of parents (e.g., family living in conditions of overcrowding, had
18 economic problems - social worker or social educator) and specific areas of intervention
19 (e.g., parents with difficulties to deal with their children's problems, children with behavioral
20 problems, few social skills, or with special educational needs - social educator or
21 psychologist). Parenting education was conducted by two members of Family Support
22 Program staff (childhood educator and psychologist). The intervention was personalized and
23 flexibly adapted to the problems defined by and for each family and child (e.g., contents per
24 session and session time). Thus the program integrates direct and close work with children in

1 small groups in pre-school, group sessions with parents and individual sessions with the child
2 and the parents at home, and the use of a variety of materials to support the activities.

3 The intervention component of Parental Relations consisted in an average of 20
4 individualized sessions with the parents at home (every two weeks). Visits typically lasted
5 between 30 and 90 min, depending on the parents and the particular activity and 15 individual
6 or group sessions in pre-school. Activities were focused on education in child development,
7 health care, nutrition and parenting education, and on providing developmental information to
8 increase parental knowledge and enhance appropriate and effective parental responses to child
9 needs, and parent–child interaction activities, through the implementation of a "one-to-one
10 curriculum" (Weikart, 1998). In addition to the home visits, parents received parenting
11 education in classes and workshops (at least once a month), video-modelling, and written
12 resources developed by the intervention team. The project ensured child care while the
13 parents participated in the individual or group parenting education activities, which were
14 delivered at convenient schedules for the parents (i.e. outside working hours). No monetary
15 compensation was provided to the families.

16 The intervention component Development of Child Cognitive, Social and Personal
17 Skills consisted in 52 sessions that held two times per week, with a duration of thirty minutes
18 each, for a total of one hour of application per week, which is consistent with international
19 guidelines (Euser et al., 2015). These sessions were conducted in groups of four to six
20 children guided by an educator within the school system hired by the institution specifically to
21 develop this part of the program. This component aimed to improve the cognitive, social and
22 personal development of children in two main areas: the area of Personal and Social
23 Education which focused primarily on skills of self-esteem, identity, expression of feelings
24 and interpersonal relationships; and the Cognitive area which focused on problem-solving
25 abilities, language, performance, and strategic planning skills.

1 The project team received literature and training during two weeks before the
2 intervention in the use of the tools and methodologies of the program. To monitor program
3 implementation, there were also monthly regular meetings (training and supervision) of the
4 academic team with the implementation team. These meetings focused on: assessing the
5 involvement of program participants; case supervision, generating information to ensure
6 successful implementation and adaptation (i.e. small changes made during the activities
7 implementation); improving the delivery of the program on an ongoing basis; providing
8 feedback to guide the practices of the professionals; verifying the perspectives of the
9 professionals on the value of the different components and activities in progress. The program
10 sessions were all implemented.

11

12 **Measures**

13 **Questionnaire for Evaluating Maltreatment and Neglect (Calheiros, 2006).** This
14 instrument was filled out by the team (e.g., social worker, educator and psychologist)
15 involved with families and evaluates parental abuse and various types of neglect in children
16 between 0 to 16 years: psychological and physical abuse (physically aggressive interaction,
17 methods of physical violence, verbal interaction, coercive discipline/punitive methods,
18 evaluation standards), physical neglect (clothing, hygiene and physical welfare, living
19 conditions and hygiene, food, physical health monitoring), educational neglect (development
20 needs, monitoring mental health, school tracking), and lack of supervision (additional
21 alternative monitoring, secure environment, supervision, social and moral development,
22 relationship with the attachment figures). This measure presents good internal consistency,
23 presenting in this sample the following Cronbach's alpha - Physical Neglect (.86),
24 Psychological and physical abuse (.86); Lack of supervision (.73); Educational Neglect (.76),

1 similar to those found by the author in the study of construction and validation of the
2 instrument.

3 **Scales of Mental Development of Ruth Griffiths 2-8 (Luiz et al., 2006).** This
4 instrument assesses the overall development of children between 2 and 8 years in six specific
5 areas: locomotion (e.g. "Able to go upstairs using alternating feet"), personal-social (e.g.
6 "Says their name when you ask"), hearing and language (e.g. "Defined by use of language"),
7 hand-eye coordination (e.g. "Fold in half a square of paper, by imitation"), performance (e.g.
8 "Twists a toy"), and practical reasoning (e.g. "Do you know the number of fingers on each
9 hand"). This instrument was filled out by the psychologist in day care setting. As regards the
10 Portuguese psychometric characteristics of the Scales of Mental Development of Ruth
11 Griffiths 2-8, the scale presents values of internal consistency of the different subscales
12 between .90 and .97 and a global scale internal consistency of .99.

13

14 **Data analysis**

15 In the data analysis, we performed analyses of variance with repeated measures (2
16 (intervention vs control) X 2 (pre intervention T1 vs. post intervention T2) for all dimensions
17 assessed. The program effectiveness is indicated by significant interaction effects. Then, we
18 calculated the size of the effect (Cohen's d) in meaningful interactions, to qualify the
19 magnitude of effect as small, medium or high (Rodrigo, Máiquez, Correa, Martín, &
20 Rodríguez, 2006). Finally, we conducted analysis of variance for each group to see if there
21 were differences between the pre to post evaluation in each group separately.

22

23

Results

24 The ANOVAs with repeated measures showed an interaction effect in three
25 dimensions of maltreatment: physical neglect ($F_{(1.33)} = 4.36, p = 0.045$), psychological and

1 physical abuse ($F_{(1,33)} = 6.85, p = 0.013$) and lack of supervision ($F_{(1,33)} = 11.57, p = 0.002$).
 2 Specifically, physical neglect (e.g., clothing, hygiene and physical welfare, living conditions
 3 and hygiene, food, physical health monitoring), psychological and physical abuse (e.g.,
 4 aggressive interaction, coercive discipline/punitive methods, evaluation standards) and lack of
 5 supervision (e.g., additional alternative monitoring, secure environment, supervision, social
 6 and moral development, relationship with the attachment figures) decreased in the
 7 intervention group, while the control group remained, diminished slightly, or increased. This
 8 corresponds to a high effect size in the first two scales (*Cohen's d* = -0.71, and *Cohen's d* = -
 9 1.01) and a medium effect size in the last (*Cohen's d* = -0.48).

10 INSERT TABLE 1

11 Group analyses reinforce this result indicating that only in the intervention group,
 12 physical neglect ($t_{(17)} = 2.15, p = 0.046$), psychological and physical abuse ($t_{(17)} = 2.80, p =$
 13 0.012) and the lack of supervision ($t_{(17)} = 3.38, p = 0.004$) decreased from pre to post-test.

14
 15 Regarding the child development measure, the ANOVAs with repeated measures
 16 indicated the absence of interaction effects in all subscales, except on hearing-language scale.
 17 The interaction effect on the hearing-language scale ($F_{(1,35)} = 3.02, p = 0.091$) showed an
 18 increase in the intervention group and a decrease in the control group during the intervention.
 19 This effect corresponds to a small effect size (*Cohen's d* = 0.31).

20 INSERT TABLE 2

21 Group analysis indicated that the intervention group improved between the pre and
 22 post assessment in performance ($t_{(18)} = -4.25, p = 0.000$), practical reasoning ($t_{(18)} = -2.34, p =$
 23 0.031) and global development ($t_{(18)} = -2.52, p = 0.021$) dimensions while the control group
 24 only improved in practical reasoning ($t_{(17)} = -2.65, p = 0.017$).

25

1 the program seemed showed slight improvements in areas referring to increased vocabulary,
2 defining more objects by use, appointing more figures, and building larger and more complex
3 sentences. However, the observed effect size was small. On the one hand, this suggests that
4 the intervention was not effective with regard to impacts on children outcomes. On the other
5 hand, it is possible that the effects on children might be observed only after a longer time-
6 span, since the improvement in parenting functioning and practices may exert a positive
7 influence in the longer term, continuously and cumulatively in the children's development.
8 Also, there may be sleeper effects, meaning that the intervention effects may increase over
9 time, because parents would need some more time to practice new skills.

10 Considering the intervention short term effects and the comparison group results, we
11 can hypothesize that without the intervention this sample might maintain the same parental
12 practices. Indeed, parental practices may follow the same patterns during the child
13 development (e.g., McNally, Eisenberg, & Harris, 1991), and even through generations (e.g.,
14 Bert, Guner, & Lanzi, 2009). Without any intervention, abusive and neglectful practices tend
15 to endure, which have negative effects on the child development on the short, medium and
16 long terms (Hildyard & Wolfe, 2002). Our findings are consistent with results of other
17 interventions that reinforce the importance and effectiveness of attunement intervention
18 programs (e.g., Macbeth, Law, McGowan, Norrie, Thompson, & Wilson, 2015) for parents
19 and for children (Dagenais, Bégin, Bouchard, & Fortin, 2004; Letarte, Normandeau, & Allard,
20 2010; Ponzetti, Charles, Marshall, & Hane, 2008). Also, regarding the total length of the
21 sessions (26 hours) and duration (nine months) of the program, our study is consistent with
22 the literature which proposed interventions with a moderate number of sessions (16–30) and
23 months (6–12) (Euser, et al., 2015). Most programs implemented and robustly assessed have
24 been developed in North America, which means that the knowledge of what works (and what
25 does not) is mostly limited to specific cultural contexts (e.g. Donelan-McCall, Eckenrode, &

1 Olds, 2009). However, it is important to evaluate these interventions in contexts with different
2 historical, cultural and social backgrounds (Moran, Ghate, & Van der Merwe, 2004). Any
3 adaptation and implementation of the FSP in other countries or populations should be attuned
4 with the parents and children needs and characteristics, using procedures like the one used in
5 this program (ADAPT-ITT model, Storer, Barkan, Sherman, Haggerty, & Mattos, 2012),
6 which offers a set of steps for adapting evidence-based programs in social and educational
7 service settings.

8 **Limitations**

9 In terms of the limitations of the study, we highlight the absence of a follow-up
10 assessment and the absence of a real implementation evaluation, to understand which features
11 are essential to the effectiveness of the program, as well as to whom and under what
12 conditions this program is more or less effective (e.g., Stolk et al., 2008). In this study, we
13 used an experimental pretest-posttest design and the subjects were randomly assigned to
14 groups. Although this design is adequate to evaluate the intervention effects, it lacks a process
15 and follow up evaluation. Concerning fidelity, the feedback from the team meetings was that
16 although some adaptations and adjustments were made in some activities to ensure a more
17 effective delivery (i.e. taking into account specific characteristics of children and their
18 parents), in general the program was implemented as initially designed. However, the
19 information collected was anecdotal. Thus, there is no evidence concerning the program
20 fidelity, and it is not possible to conclude if the short-term effects maintain, disappear, or
21 increase over time. In future studies, further data with regard to the total number of sessions,
22 periodicity, content type, contents per session, methods and techniques need to be gathered
23 and analyzed. We also stress the small size of the sample that reduces the power of the
24 analyses, and the lack of assessment by blind raters. In spite of using different sources of
25 information (one of the measures was directly applied to the children by the psychologist, and

1 the other measure was completed by the team based on the observation, interviews and case
2 records), these professionals were the ones applying and assessing the program. An important
3 step for future research would be to replicate these results with multi-informant measures and
4 multiple methods (e.g., observations of parent-child interactions), which could give more
5 information on the nature of the relationships.

6 It is also recommended that future programs in this topic are evaluated not only in
7 terms of their impact but also the process of implementation, in the medium and long term,
8 with a larger sample size, and with different respondents. This may allow for understanding
9 the wider impacts of such programs and outline the factors that contribute the most to their
10 effectiveness. Despite these limitations, the program showed promising findings with regard
11 to improving parental practices of family functioning, allowed for proposing several
12 recommendations and principles for interventions (e.g., comprehensiveness, specificity and
13 evaluation), and showed a promising methodology to be followed in the context of family
14 social services.

15

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17 Conflict of Interest: The authors declare that they have no conflict of interest.

18 Research involving Human Participants and/or Animals: All procedures performed in
19 studies involving human participants were in accordance with the ethical standards of the
20 institutional and/or national research committee and with the 1964 Helsinki declaration and its
21 later amendments or comparable ethical standards.

22 Informed consent: Informed consent was obtained from all individual participants
23 included in the study.

24

25

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