



Eat2beNICE

Effects of Nutrition and Lifestyle on Impulsive, Compulsive, and Externalizing Behaviours

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D 2.3– Manuscript: Effects of elimination diet on symptoms of impulsivity, compulsivity and aggression

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Executive Summary

In this study we assessed the short- and long-term effects of an elimination diet (ED) versus a healthy diet (HD) on reducing impulsive, compulsive, and aggressive behaviour. A total of N=165 children (5-12 years) with ADHD were randomized to either ED (N=84) or HD (N=81). A non-randomized comparator arm was included with N=58 children being treated with Care as Usual (CAU). The primary outcome was a 5-point ordinal measure of respondership based on a combination of parent and teacher ratings on ADHD and emotion regulation, determined after five weeks of treatment (short-term) and at 1 year prospective follow-up (long-term). Ordinal regression analyses were done on an intention to treat basis.

After five weeks, fewer ED (35%) than HD (51%) participants showed a partial to full response, despite overall good to excellent treatment adherence (>88%) and comparable high parental prior believes. CAU-preferring participants responded more often favorably (56%) compared to ED- but not HD-participants. Small to medium improvements in physical health (blood pressure, heart rate, somatic complaints) were found in response to ED/HD versus decrements in response to CAU (74% received psychostimulants).

Follow-up rate at 1 year was high for all three treatment-trajectories (~90%). A minority of participants (<20%) still follow ED or HD without switch to – or adding- CAU. Adherence to the dietary treatments in the long-term is good to excellent (>73%) for these participants. Only ~8% of the full responders to the ED still followed the ED at 1-year follow-up compared to ~55% of HD participants.

We conclude that for school-aged children with a combined presentation of ADHD and ED, a HD might be considered in ADHD care as a starter or as co-treatment. Long-term prospective follow-up results are comparable to those of children starting immediately with CAU, yet with substantially lower psychostimulant rates (~40% vs ~75%). Furthermore, while a ED is effective for some children, a HD appears to be at least as effective and easier to adhere in both the short-and long-term. Lastly, the overall modest results of the ED suggest that for the majority of children the link between nutrition and behaviour is not rooted in food-allergies /-sensitivities.

Abbreviations

ADHD	Attention deficit / hyperactivity disorder
RCT	Randomized Controlled Trial
ED	Elimination diet
HD	Healthy diet
CAU	Care as usual
ITT	Intention-to-treat



1. Deliverable report

Rationale

The role of nutrition is an increasingly important research area in psychiatric disorders like Attention-Deficit/Hyperactivity Disorder (ADHD) which affects about 7.2% of children and adolescents. A dietary approach frequently studied as potential intervention for ADHD is an elimination diet (ED) in which a limited number of foods are allowed to be consumed. Its rationale is that ADHD behaviors may be elicited by systemic adverse reactions to certain food allergens and potential food triggers. Results of two meta-analyses demonstrated that an ED may significantly reduce ADHD problems in about 30% of children. Reductions in comorbid oppositional behaviors were also reported, potentially attributable to an improvement in emotion regulation.

However, several vital clinical issues remain unanswered. Specifically, it is unknown whether an ED shows superior effects when compared to an active control group with comparable impact on dietary constraints and similar non-specific factors such as parental treatment expectations. Studies also have not addressed the feasibility of implementing dietary treatments in clinical practice. Finally, an understanding is still lacking of which factors might predict response to ED.

Study design

In this study we assessed the short- and long-term effects of an elimination diet (ED) versus a healthy diet (HD) according to WHO health guidelines on reducing impulsive, compulsive, and aggressive behaviour. A total of N=165 children (5-12 years) with ADHD were randomized by means of minimization (1:1) to either ED (N=84) or HD (N=81) within two Dutch child and adolescent psychiatry centers. The design included a non-randomized comparator arm including N=58 children being treated with Care as Usual (CAU) (See Figure 1). Treatment allocation was unblinded. The primary outcome was a 5-point ordinal measure of respondership based on a combination of parent and teacher ratings on ADHD and emotion regulation, determined after five weeks of treatment.

All participants in the dietary treatment arms were allowed to continue with dietary treatment after 5 weeks as well as switch to –or add- CAU. Only full and partial responders to the dietary treatment were encouraged to continue the diet. Non-randomized CAU participants were not offered the possibility to switch to a dietary intervention to allow unbiased examination of effectiveness of the diet-trajectories.

Short-term results

Ordinal regression analyses were done on an intention to treat basis. After five weeks, fewer ED (35%) than HD (51%) participants showed a partial to full response, despite overall good to excellent treatment adherence (>88%) and comparable high parental prior beliefs (Figure 2). CAU-preferring participants (74% receiving stimulants) responded more often favourably (56%) compared to ED- but not HD-participants.

Small to medium improvements in physical health (blood pressure, heart rate, somatic complaints) were found in response to ED/HD versus decrements in response to CAU (Figure 3).

Results prospective follow-up at 1 year

Follow-up rate was high for all three treatment-trajectories (~90%). A minority of participants (<20%) still follow ED or HD without switch to – or adding- CAU. Adherence to the dietary treatments in the long-term is good to excellent (>73%) for these participants. Only ~8% of the full responders to the ED still followed the ED at 1 year follow-up compared to ~55% of HD participants. The number of adverse events is negligible.



ITT results of the prospective one-year follow-up demonstrate that an ED (+CAU) is not superior to HD (+CAU) in improving ADHD and ER behavior. In fact, the pattern of improvement on ADHD and ER problems is in favor of offering HD(+CAU). More HD(+CAU) participants show (partial) improvement after one year compared to ED(+CAU) participants, whereas more ED(+CAU) participants show ambiguous effects (Figure 4).

Comparable 1-year effects of treatment with HD(+CAU) and CAU were found, which is somewhat remarkable given that CAU participants were more often treatment-naïve and therefore probably 'easier to treat' than HD (and ED) participants. Children that started immediately with CAU were treated more often with psychostimulants at 1 year follow-up (~75%) compared to children that started with the HD and were allowed to switch to –or add- treatment with psychostimulants (~40%).

Conclusions and clinical implications

For school-aged children with a combined presentation of ADHD and ED, a HD might be considered in ADHD care as a starter or as co-treatment. Long-term prospective follow-up results are comparable to those of children starting immediately with CAU, yet with substantially lower psychostimulant rates (~40% vs ~75%).

While an ED is effective for some children, a HD appears to be at least as effective and easier to adhere in both the short-and long-term.

The overall modest results of the ED compared to the HD suggest that for the majority of children the link between nutrition and behaviour is not rooted in food-allergies /-sensitivities.

2. Tables and other supporting documents where applicable and necessary

Figure 1. Study flow chart

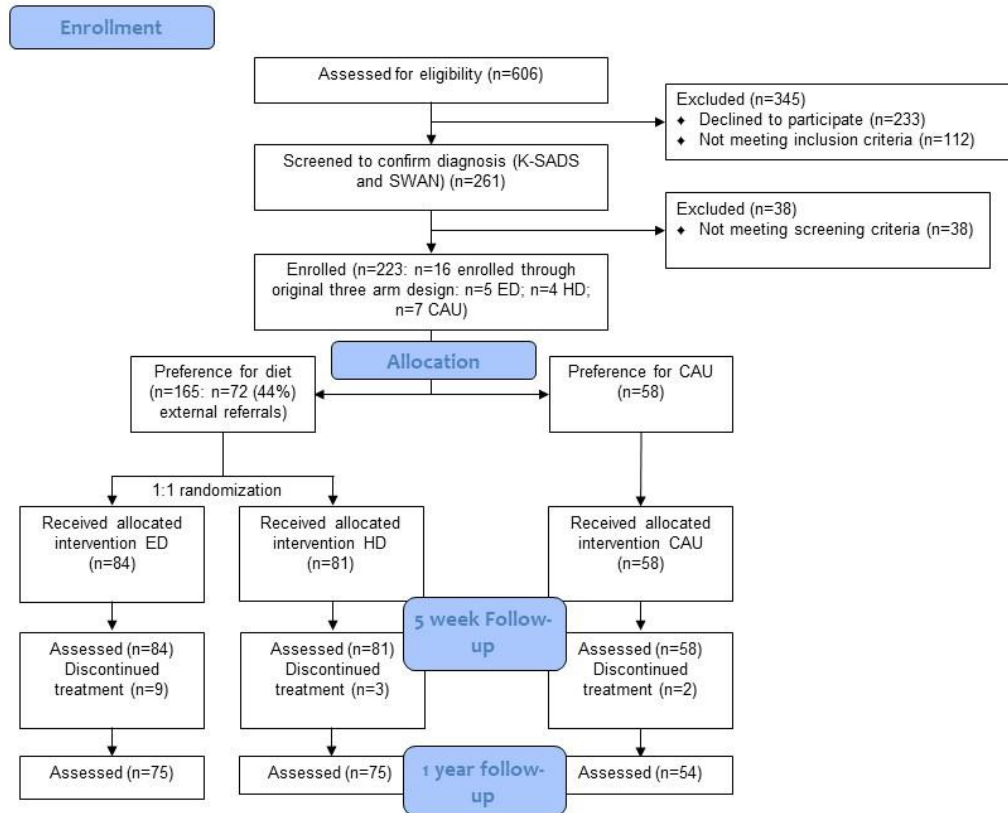


Figure 2. Respondership after 5 weeks of treatment.

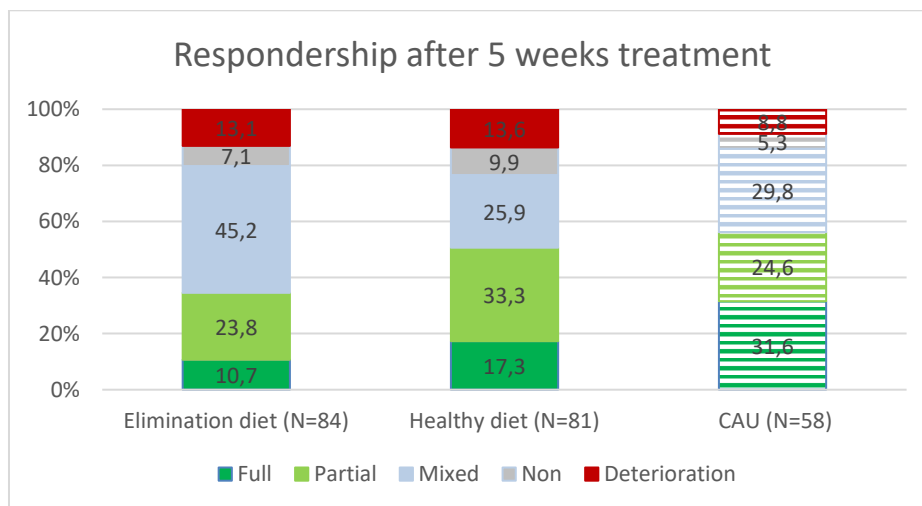




Figure 3. Effects on physical health after 5 weeks of treatment.

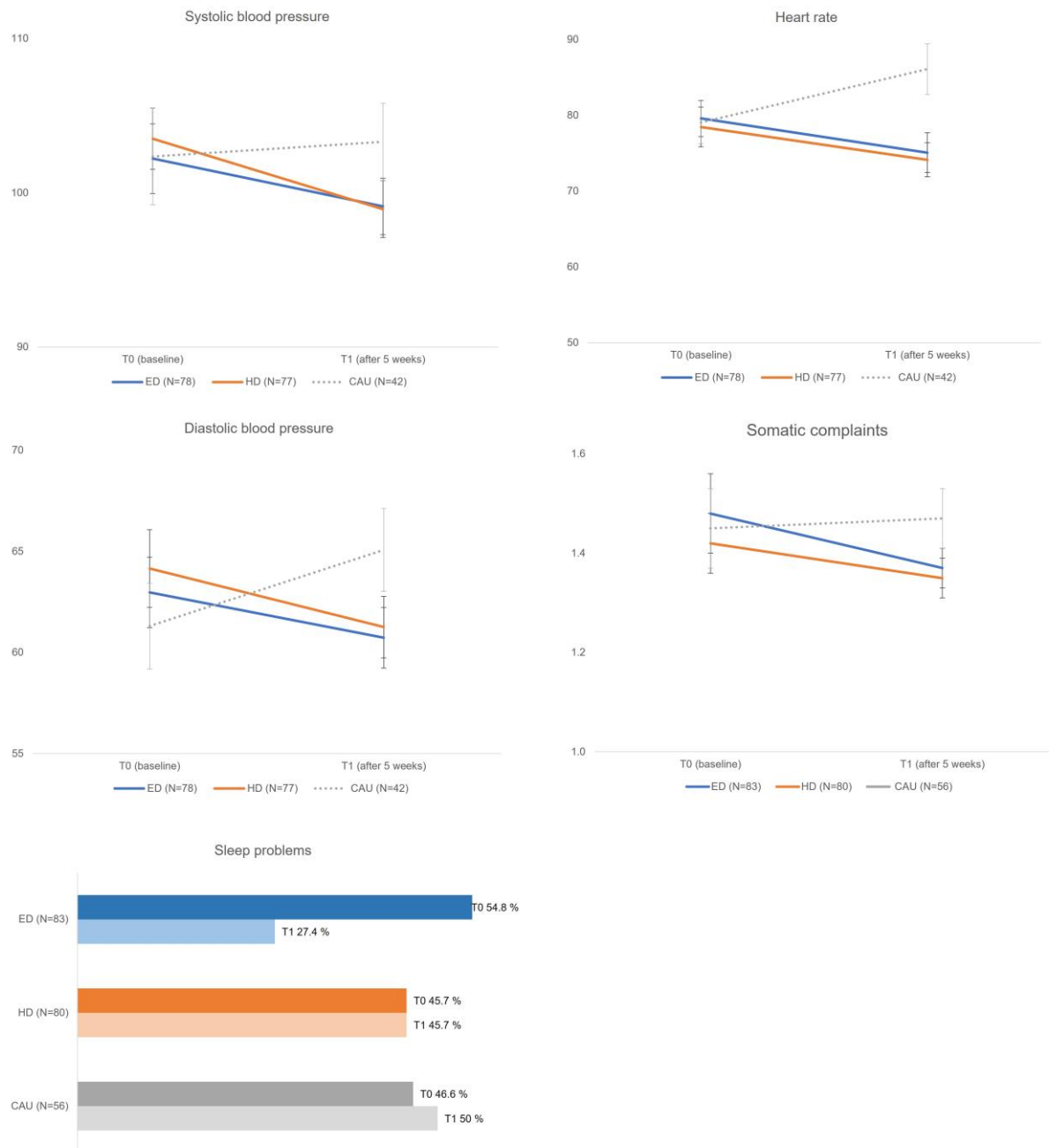




Figure 4. Respondership based on treatment trajectories after prospective follow-up at 1 year.

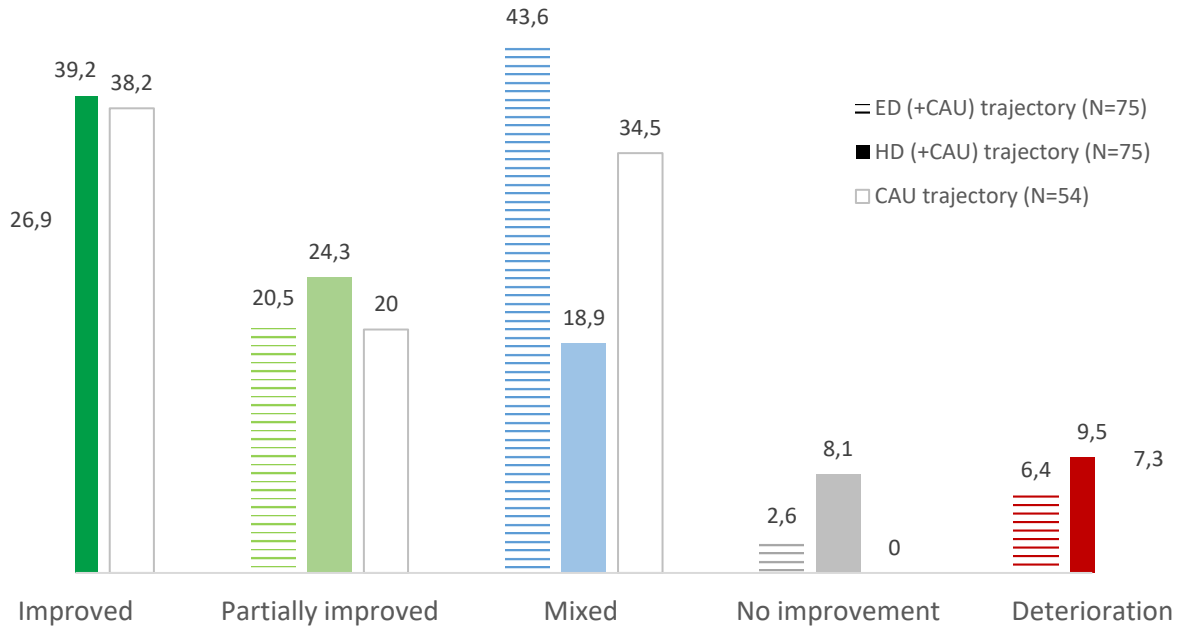
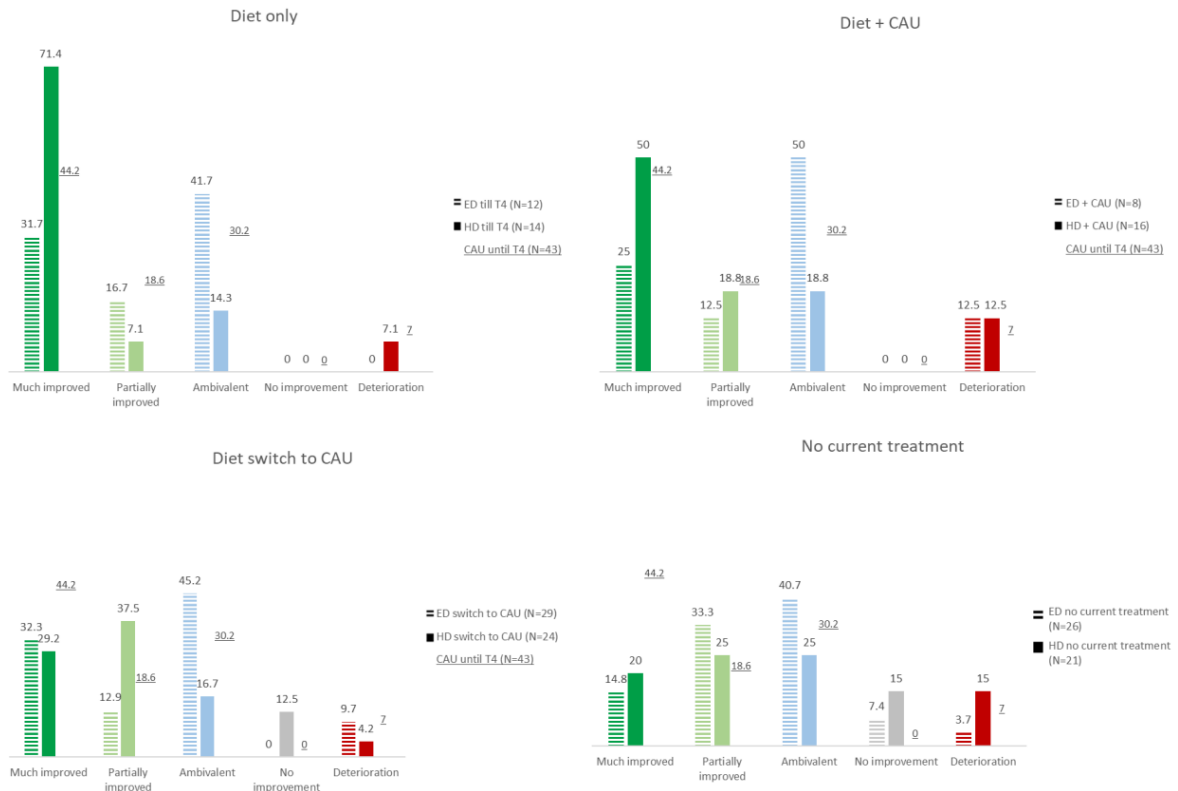


Figure 5. Respondership stratified by ongoing treatment at 1 year follow-up.





3. Acknowledgement and Disclaimer

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