

Unique Protocol ID: IBSR-Stuttering 11/2017

Brief Title: IBSR Intervention for Adults Who Stutter

Official Title: The Effect of "Inquiry Based Stress Reduction" (IBSR) on the Overall Stuttering Experience, Quality of Life and Psychological Indicators Among Adults Who Stutter a Randomized Controlled Clinical Trial

Date: November 1, 2017

Sponsors: Tel-Aviv Sourasky Medical Center affiliated to Tel-Aviv University, and the Israeli Stuttering Association (AMBI).

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Summary

Stuttering is a speech disorder that can cause disturbances in the timing and flow of speech. It is often accompanied not only by verbal difficulties but also by negative impact on several psycho-social aspects in the life of the people who stutter.

Recently, clinical evidences have shown the effectiveness of Inquiry Based Stress Reduction (IBSR) technique to improve psychosocial symptoms and enhance well-being in clinical and non-clinical samples. IBSR, the clinical application of Byron Katie's "The Work", enables individuals to mindfully spot and investigate in a systematic and comprehensive manner thoughts that lead to stress and suffering by a series of questions and turnarounds. IBSR was found to have significantly positive influence on the quality of life, mental well-being and stress management in a variety of populations which suffer from elevated levels of stress, suffering, tension and anxiety, and to enhance resilience of non-clinical general population.

In our research we hypothesized that:

1. Adults who stutter will have high levels of anxiety, and low levels of psychological flexibility and satisfaction with life.
2. IBSR intervention will improve experience of stuttering in adults who stutter.
3. IBSR will decrease anxiety levels and enhance psychological flexibility and satisfaction with life.

Study Design

Study Type: Interventional (Clinical Trial)

Primary Purpose: Treatment

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: None (Open Label)

Allocation: Randomized

Enrollment: 56 subjects

Arms and Interventions

Arm	Assigned Interventions
Experimental: Inquiry Based Stress Reduction (IBSR) workshop	<p>Behavioral:</p> <p>Participants of this group received an IBSR intervention workshop. The IBSR intervention workshop included weekly group meetings (3.5 hours/meeting) for 12 weeks. During the workshop, participants were encouraged to identify and inquire their stressful thoughts. Using self-inquiry practices participants were taught to increase awareness of their thoughts and feelings, to observe their emotional and physical responses during situations perceived by them as stressful, and allow their mind to return to its true, peaceful, creative nature. Through the process of self-inquiry, participants took an active role in investigating their stressful thoughts, and by this regulated their stress and managed symptoms and emotions, thus enabled them to cope better with the psycho-social consequences of the stuttering.</p> <p>Other Name: "The Work" meditation (Byron Katie)</p>
No Intervention: Control group	<p>None:</p> <p>Participants of this group did not take a part in the workshop.</p>

Outcome Measures

Primary Outcome Measure:

1. Overall Assessment of the Speaker's Experience of Stuttering for Adults (OASES-A) [Time Frame: 1) Before the workshop (T1), 2) Immediately after the workshop (T2), 3) One month after the workshop (T3)].

The purpose of OASES-A questionnaire is to assess the overall stuttering experience of adults who stutter. It quantifies the quality of life, satisfaction and overall personal experience of the adult in his daily coping with stuttering. The items in the questionnaire are divided into four main sections: 1. General information on stuttering awareness and perception. 2. Reactions to stuttering. 3. Communication in daily situations. 4. Quality of life.

The OASES-A total score is obtained by summing the scores of the four different sections. In this trial we used the Hebrew version of this questionnaire. OASES-A total score and the score for each of the sections (in the Hebrew version) is ranging from 1.0 to 5.0. The score rates the severity of the stuttering experience, where 1.0 indicates a mild impact rating and 5.0 a severe impact rating (higher scores indicate a more negative impact of stuttering) (Freud et al., 2017; Yaruss & Quesal, 2006).

Secondary Outcome Measures:

1. State-Trait Anxiety Inventory (STAI) [Time Frame: 1) Baseline (Before the workshop (T1)). 2) Immediately after the workshop (T2). 3) One month after the workshop (T3).]

The STAI questionnaire assess the tendency of adults to experience anxiety and to inspect their sensitivity to anxiety-provoking situations. The questionnaire distinguishes between two scales of anxiety: anxiety as a state and anxiety as a trait. State anxiety is a person's tendency to experience anxiety in certain situations and times, depending on their context. Trait anxiety is a person's constant and stable tendency to experience anxiety frequently.

Each item is rated on a 4-point Likert scale. After completing the questionnaire, items scores are added to obtain total scores. Responders receives 2 separate total scores, one for each of the scales. The maximum score for each scale is 80 and the minimum score is 20. In both scales, scores between 20 to 40 is considered normal in the general adult population. The higher the score, the higher the anxiety level (Spielberger et al., 1970; Taychman & Malinek, 1984).

2. Psychological Flexibility Questionnaire (PFQ) [Time Frame: 1) Baseline (Before the workshop (T1)). 2) Immediately after the workshop (T2). 3) One month after the workshop (T3).]

The aim of PFQ questionnaire is to measure the psychological flexibility of the test responder. Psychological flexibility describes a person's ability to be open, to perceive change as positive, to focus on the present and to change or persist in

behavior according to changes of internal and external circumstances. The questionnaire consists of 20 items rated on a 6-point Likert scale. Each item is associated with one of 5 factors that refers to a significant domain in psychological flexibility. The 5 factors are: 1. Positive perception of change. 2. Characterization of the self as flexible. 3. Self-characterizing as open and innovative. 4. A perception of reality as dynamic and changing. 5. A perception of reality as "multifaceted". The score of the questionnaire is calculated based on the mean of the 20 items. Higher score indicates high level of psychological flexibility (Ben-Itzhak et al., 2014).

3. Satisfaction with Life Scale (SWLS) [Time Frame: 1) Baseline (Before the workshop (T1)). 2) Immediately after the workshop (T2). 3) One month after the workshop (T3).]

The SWLS questionnaire evaluates the person's overall satisfaction with life, based on personal criteria that he defined for himself and based on his perception of life. In the questionnaire, there is 5 items that the subjects are required to rate using a 7-point Likert scale. The five items are summed to create a total score that ranged from 5 to 35, with a higher score indicates greater satisfaction with the subject's life. A final grade in the range of 30-35 is a very high score, indicating a person with great satisfaction and very satisfied with his life (Diener, 1994; Diener et al., 1985).

Eligibility Criteria

Ages Eligible for Study: 18 Years and older

Sexes Eligible for Study: All

Inclusion Criteria:

- Diagnosis of either developmental or acquired stuttering.
- Capability to understand and fill out the study outcome instruments and informed consent form.

Exclusion Criteria:

- Diagnosis of severe mental illness.
- Inability to understand or read Hebrew.
- Subjects who declare they cannot take a part in the trial throughout its whole duration.

Contacts/Locations

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References

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