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Mindfulness and metacognition in facing with fear of recurrence: A proof-of-concept study with breast-cancer women

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Abstract

Objective: Fear of recurrence is a crucial issue in cancer care. On the one hand, the increase of cancer-survival rates and complexity of care is exposing patients to this type of fear. On the other hand, it is a distressing and recurrent psychosocial risk that affects quality of life and adherence to follow-up. Patients should have access to targeted psychological interventions aimed at reducing or preventing fear of recurrence. This mixed-methods pilot study reports the preliminary results of a novel mindfulness- and metacognition-based intervention specifically targeting fear of recurrence.

Methods: The study was composed of an individual (n = 76) and a group (n = 38) intervention, both lasting 8 weeks, that were evaluated through a preassessment and postassessment and a 1-month follow-up. We enrolled women recovering from breast cancer (n = 114) in follow-up care, with significant psychosocial distress. Patients with more severe psychopathology were assigned to the individual treatment, whereas the less severe ones were assigned to the group treatment. We explored the distress and the fear of recurrence through standardized measures and in-depth qualitative interviews.

Results: Results showed that depressive, anxious, and post-traumatic symptoms were reduced significantly in the entire sample. Patients reported a significant reduction of fear of recurrence, which was described in terms of loss of control, increase of uncertainty, and decrease of metacognitive and interpersonal skills.

Conclusions: Although further studies are needed, these findings provide preliminary proof-of-concept results for the potential of integrated mindfulness- and metacognition-based interventions to reduce fear of recurrence in cancer patients.

KEYWORDS

breast cancer, cancer, compassion, fear of cancer recurrence, metacognition, mindfulness, oncology

1 | BACKGROUND

Worldwide there are nearly 43.8 million cancer survivors. One in eight men and one in 10 women will develop a cancer in their lifetime.[1] Adjustment to life-after-treatment has become a crucial challenge for health services, with patients facing at least three major issues: fatigue, financial burden, and fear of recurrence.[2]

There is a growing body of evidence that fear of cancer recurrence (FCR) is a common psychosocial problem with 42% to 70% of cancer survivors reporting clinically significant levels.[3] Considering the complex trajectory of a cancer patient and the novelty of this area of research, we acknowledge that FCR can be framed through different and partially diverging theories.[4] Regardless, there is a consensus on many relevant components: (a) FCR is an adaptive process that may turn to be maladaptive; (b) it can manifest as different symptoms and disorders (eg, anxiety disorder and trauma-related disorder) or may exacerbate preexisting mental health conditions; (c) perseverative-thinking processes such as worry are recurrent maintenance factors; (d) different internal or external cues trigger specific FCR cognitive schemas; (v) family and social environment can influence the appraisal process of cues and reinforce maladaptive schemas; (vi) FCR may vary over time, and being female, young, and socially isolated seem to be risk factors.[4-8]

Though we lack robust evidence, there is emerging literature showing that cognitive-behavioral therapy (CBT) may represent an effective strategy to reduce FCR, especially models such as metacognitive therapy (MCT), mindfulness-based interventions (MBIs), and acceptance and commitment therapy (ACT).[4-8] These types of interventions are focused on a process-based and self-reflexive approach[9] that may offer a flexible strategy in reducing FCR or in promoting an adaptive adjustment.

In the last few years, we have tried to develop an integrated CBT program for women with breast cancer in follow-up care. The program, Metacognitive Awareness in Cancer Setting (MACS), represents a novel mindfulness- and metacognition-based intervention for survivors. The first version[10] included an individual intervention mainly based on MCT[11] and a group intervention mainly based on MBIs.[12,13] In order to better support patients in dealing with post-traumatic and interpersonal concerns, we have included in the present revised version a narrative exposure therapy (NET)[14] and metacognitive interpersonal therapy[15] (MIT) module, respectively. To the best of our knowledge, this is the first study aimed at integrating mindfulness- and metacognition-based interventions for cancer patients.

2 | METHODS

2.1 | Sample

The study sample (n = 114) was recruited through a convenience sampling. All of the subjects were referred to the same cancer unit at the Santa Maria Annunziata Hospital in Florence. Patients did not pay for the intervention and did not receive any credit or benefit in return for their participation. The sample included two subsamples, patients who were assigned to the group (G_α; n = 38) or to the individual (G_β; n = 76) intervention. Table 1, 2.

TABLE 1 Descriptives of the sample

Age	Overall Sample 53.42 (SD = 9.14)	Group Intervention 54.48 (SD = 7.84)	Individual Intervention 52.90 (SD = 9.73)
Education			
Middle school or less	20	9	11
High school	21	7	14
College	44	15	29
Advanced degree	29	9	20
Relationship status			
Single	15	6	9
Married	67	21	46
Stable relationship	34	13	21
Drop-outs			
Total rate	8	3	5
Prior to t_1	5	3	2
Prior to t_2	3	0	3
Reason to drop-out			
Personal decision	3	1	2
Logistical or work reason	4	2	2
Reason unknown	1	0	1

TABLE 2 Outcomes across time

	Mean	Standard Deviation
DT		
t_0	6.693	1.2122
t_1	1.368	0.9137
t_2	1.392	0.9612
HADS-Anxiety		
t_0	11.58	3.372
t_1	2.49	1.686
t_2	2.35	1.762
HADS-Depression		
t_0	13.16	3.734
t_1	3.01	1.964
t_2	2.71	2.160
IES-R		
t_0	20.06	6.478
t_1	7.48	4.923
t_0	3.92	3.872
MAAS		
t_0	4.0959	0.92252
t_1	5.0575	0.49224
t_2	5.0531	0.46609

Abbreviations: DT, Distress Thermometer; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale—Revised; MAAS, Mindful Attention Awareness Scale.

2.2 | Study design and protocol

The study was conducted according to the Declaration of Helsinki; the protocol was approved by the institutional review board (reference decision 281118). Eligible patients were women who (a) were diagnosed with stages 0 to 3 breast cancer, (b) had completed adjuvant treatments 2 months to 2 years previously, (c) had been treated with curative intent and were currently disease free, (d) were aged between 18 and 65 years old, (v) were scored in the clinical range on the Distress Thermometer (DT) (greater than or equal to 4) and anxiety subscale (greater than or equal to 8) of the Hospital Anxiety and Depression Scale (HADS). Exclusion criteria were the following:

(a) being diagnosed with intellectual disability, schizophrenia, or bipolar disorder; (b) receiving psychological and/or psychopharmacological treatment.

Assignment to the individual (G_β) or group (G_α) intervention was done as follows: (a) patients with high psychopathology (one severe or two moderate mental disorders) were assigned to the individual intervention; (b) patients with low psychopathology (one moderate or one or more minor mental disorders) were assigned to the group intervention. Level of severity was defined accordingly to cross-cutting symptom measures of the *Diagnostic and Statistical Manual of Mental Disorders*.[16]

Consecutive eligible patients were identified and informed by the team. Eligible patients who signed the informed consent were administered the initial assessment (t_0) and were admitted to the study. At the end of the first assessment, the patients were assigned to the individual (G_β) or group (G_α) intervention accordingly to the described criteria. At the end of the intervention, a second assessment (t_1) was performed. Finally, patients were administered the 1-month follow-up final assessment (t_2). Three different therapists performed three specific tasks: one administered the assessment; one delivered individual and group interventions; one supervised the interventions.

Treatment fidelity was assessed by specific procedures[17]: (a) we prepared a manual for the therapists and a workbook for the patients; (b) provider's qualification required at least 5 years' experience as a psycho-oncologist and mindfulness teacher; (c) we delivered weekly supervisions; (d) we defined a specific checklist for each session that was scored by the provider and revised by the supervisor; (e) we counted dropouts and assessed the reason.

2.3 | Measures

2.3.1 | Distress thermometer[18]

DT is a one-item, 11-point Likert scale represented on a visual graphic of a thermometer that ranges from 0 (no distress) to 10 (extreme distress). Patients are asked to indicate their level of distress over the course of the week prior to assessment (clinical cutoff scores[19] greater than or less than 4).

2.3.2 | Hospital Anxiety and Depression Scale[20,21]

HADS is a Likert scale composed of 14 items to which patients respond on a four-point scale (from 0 to 3) referring to symptoms within the last week. Seven of the items relate to anxiety (HADS-A), and seven relate to depression (HADS-D). Scores of 8 to 10 or more in either subscale signify the presence of a disorder. In the present sample, Cronbach's alphas for HADS-A and HADS-D were 0.81 and 0.83, respectively.

2.3.3 | Impact of Event Scale—Revised[22,23]

Impact of Event Scale—Revised (IES-R) is a 22-item self-report measure that assesses subjective distress caused by traumatic events. Items are rated on a five-point Likert scale ranging from 0 (not at all) to 4 (extremely). It yields a total score ranging from 0 to 88. Cronbach's alpha was 0.88 in the present sample.

2.3.4 | Mindful Attention Awareness Scale[24-26]

Mindful Attention Awareness Scale (MAAS) is a 15-item questionnaire scored according to a Likert-type scale with a range going from 1 to 6. The scale measures the frequency of the state of mindfulness in daily life. A single scale score averages the scores across all fifteen items. Lower scores indicate a lower mindful awareness. Cronbach's alpha was 0.85 in the present sample.

2.3.5 | Follow-up Care—Qualitative Questionnaire[27]

We included five written open questions: (a) If a friend of yours would describe you, how would he/she? (Q1); (b) Do you think your way of being, behaving, and thinking was changed after cancer diagnosis? If yes, could you please describe how? (Q2); (c) How would you describe your usual way (before cancer diagnosis) of coping with problems? By relying on which resources or strategies did you usually cope with your problems? (Q3); (d) Do you think your way of coping with problems changed after the cancer diagnosis? If yes, could you please describe how? (Q4); (e) Do you think the FCR is affecting your life? If yes, could you please describe how? (Q5).

The psychometric measures (DT, HADS, IES-R, and MAAS) were evaluated at all the three assessment phases, whereas the qualitative measures only at t_0 with the exception of Q5 that was administered at t_0 and t_1.

2.4 | Treatment

The treatment was a tailored Mindfulness-Based Cognitive Therapy (MBCT) for cancer patients in follow-up care. The protocol[28] was based on an integration with the most validated MBIs for cancer patients.[12,13,29,30] In addition, MACS includes psychoeducation, techniques derived from compassion-focused therapy (CFT[31]), MIT,[15] MCT,[11] NET,[14] and a few specifically designed components aimed at promoting metacognition[32,33] and decentering[34] (see Supplementary Appendix).

2.5 | Data analysis

The research includes quantitative psychometric data (DT, HADS, IES-R, and MAAS) and qualitative data (Follow-up Care—Qualitative Questionnaire [FC-QQ]). We explored through paired sample *t* test the differences between preassessment and postassessment within and between the two interventions (G_α and G_β) and within the whole sample. Using repeated measures ANOVA (RMANOVA), we explored the changes in mean scores over time for both of the interventions.

Qualitative data were analyzed through two consecutive methods. A framework analysis was used to identify the possible themes.[35] The framework for the analysis was developed by a researcher and then reviewed by another one. Then, in order to confirm the hypothesized themes, a computer-aided qualitative data analysis software (CAQDAS)[36] was used. A researcher independently performed a hierarchical cluster analysis based on a previous correspondence analysis of responses' words.[36] Finally, the framework analysis and the cluster analysis were compared, discrepancies solved, and a few themes were defined.

2.6 | Objectives

The objectives were to prove that MACS is

1. Suitable for patients facing FCR (attrition rate $\leq$ 10%);
2. Effective in reducing psychological symptoms over time ($\eta \geq 0.5$).
3. Useful in eliciting beliefs about FCR (themes at FC-QQ).

3 | RESULTS

3.1 | Attrition and treatment fidelity

The attrition rate was below the target value (less than or equal to 10%) in the whole sample ($n = 8$; 7.01%) and in the individual ($n = 5$; 6.57%) and group ($n = 3$; 7.89%) subsamples. We included 106 patients ($G_\alpha = 35$; $G_\beta = 71$) in the analyses. Treatment-fidelity analysis reported completion of at least 90% (93.28%) of the sessions' tasks in providers' checklists after the supervisors' revisions (G_α = 96.07%; G_β = 93.01%).

3.2 | Change in symptoms and psychometric outcomes

Paired sample *t* test explored differences for the whole group between t_0 and t_1 reporting a significant value for distress (DT; $t = 49.97$: $P < 0.001$), anxiety (HADS-A; $t = 36.18$; $P < 0.001$), depression (HADS-D; $t = 37.87$; $P < 0.001$), post-traumatic symptoms (IES-R; $t = 24.72$; $P < 0.001$), and mindful awareness (MAAS; $t = -12.50$; $P < 0.001$). Student's *t* explored differences between G_α and G_β at t_0, highlighting a significant value for distress (DT; $t = 11.37$; $P < 0.001$), anxiety (HADS-A; $t = 17.75$; $P < 0.001$), depression (HADS-D; $t = 5.00$; $P < 0.001$), post-traumatic symptoms (IES-R; $t = 3.55$; $P < 0.001$), and mindful awareness (MAAS; $t = -11.12$; $P < 0.001$).

RMANOVA was conducted to evaluate the null hypothesis that there was no change in participants' outcomes when measured before, after, and at one-month follow-up from the intervention. The results indicated a significant time effect in the whole sample for all the outcomes with an effect size ranging from.601 to.960 (see Table 3). The multivariate test including all of the outcomes together confirmed a significant time effect (Wilks' Lambda = 0.024; $F = 387.474$; $P < 0.001$; $\eta = 0.976$), and the Mauchy sphericity test reported significant values for all of the measures ($P < 0.001$; W ranging from 0.347 to 0.770). All of the pairwise comparisons between t_o and t_1, and between t_o and t_2 (and vice versa) were significant ($P < 0.001$), whereas those between t_1 and t_2 (and vice versa) were not ($P > 0.05$), with the exception of post-traumatic symptoms (IES-R; $P < 0.0001$), which demonstrated a decrease between mean score at t_1 and at t_2 (−3.566).

We then evaluated the null hypothesis in individual and group interventions. For Gα, the multivariate test including all of the outcomes together confirmed a significant time effect (Wilks' Lambda = 0.002; $F = 2510.512$; $P < 0.001$; $\eta = 0.998$), and the Mauchy sphericity test indicated significant values for all the measures ($P < 0.05$; W ranging from 0.443 to 0.627), with the exception of mindful awareness (MAAS; $P = 0.152$) and distress (DT; $P = 0.189$). For G_β, the multivariate test including all of the outcomes together confirmed a significant time effect (Wilks' Lambda = 0.003; $F = 3878.842$; $P < 0.001$; $\eta = 0.997$), and the Mauchy sphericity test indicated significant values for all the measures ($P < 0.001$; W ranging from 0.377 to 0.739), with the exception of distress (DT; $P = 0.292$). All of the pairwise comparisons, in Gα and G_β, between t_o and t_1, and between t_o and t_2 (and vice versa) were significant ($P < 0.001$), whereas between t_1 and t_2 (and vice versa), they were not ($P > 0.05$) with the exception of post-traumatic symptoms (IES-R; $P < 0.0001$), which demonstrated a decrease between mean score at t_1 and mean score at t_2 (Gα = −2.686; G_β = −4.000).

TABLE 3 Repeated measures ANOVA Wilks' Lambda

		Value	*F*	Error *df*	Partial Eta Squared (η)
Whole Sample	DT	0.040	1249.051	104.000	0.960
	HADS-Anxiety	0.074	655.161	104.000	0.926
	HADS-Depression	0.067	729.185	104.000	0.933
	IES-R	0.123	371.842	104.000	0.877
	MAAS	0.399	78.373	104.000	0.601
G_α	DT	0.025	642.953	33.000	0.975
	HADS-Anxiety	0.041	387.953	33.000	0.959
	HADS-Depression	0.091	165.811	33.000	0.909
	IES-R	0.163	84.770	33.000	0.837
	MAAS	0.547	13.674	33.000	0.453
G_β	DT	0.020	1690.244	69.000	0.980
	HADS-Anxiety	0.060	544.782	69.000	0.940
	HADS-Depression	0.41	811.343	69.000	0.959
	IES-R	0.093	336.051	69.000	0.907
	MAAS	0.224	119.356	69.000	0.776

Abbreviations: DT, Distress Thermometer; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale—Revised; MAAS, Mindful Attention Awareness Scale. For all the scales/subscales hypothesis degrees of freedom were 2000, significance less than 0.001, observed power 1000.

3.3 | Beliefs about cancer and recurrence

Answers were analyzed together (ie, aggregating the responses to the five questions) so as to increase the number of items included in the CAQDAS analyses and singularly (ie, aggregating only the responses to a specific question). We report only the themes (ie, clusters) that were significant:

1. *Unchanged Coping Style*: 42 patients (39.62%) reported that their way of being, behaving, and thinking (Q3) and coping style (Q4) was unchanged. Such a group frequently is composed of verbal descriptors referring to a sense of self-efficacy: "I am strong enough, determined, and aimed at thinking positive" (Q1). This theme includes patients reporting both high and low levels of distress and FCR.
2. *Emotional-relational Coping Style*: a significant group of sentences referred to a specific coping style, which seems to be comprised of emotional and relational components. Such a theme includes patients who have changed their coping style after diagnosis and patients who have not. On one hand, they describe the need and the usefulness of expressing and elaborating their emotion (Q4: "It seems I'm more emotional, I cannot bury what I feel"). On the other hand, they affirm that relatives, friends, and acquaintances are the most useful resources they have, and that the act of being in touch with them is the crucial factor in their recovery (Q3:"I have rediscovered my family").
3. *Diagnosis as a Watershed*: a subgroup of patients reported a very usual post-traumatic narrative of their lives that seems to be inexorably divided into two separated parts, that is, before and after cancer diagnosis (Q4: "that day was a watershed"). On one hand, this watershed theme seems to channel the future in terms of either a high-worry and -anxious FCR (Q5: "how can you not think about the future?) or a sort of helplessness that shapes FCR (Q5: "I have to accept. It will come again"). On the other hand, it frequently focuses on practical and instrumental coping styles (Q4: "the real change was and still is how to deal with physical and economic side-effects").

By analyzing the clusters, we hypothesized two main dimensions (ie, the axes of the Euclidean space where the clusters are embedded):

1. *Diagnosis Effect on Coping Style*: the *x* axis probably refers to how cancer diagnosis changed patients' lives. We assume a continuum between narratives of a relevant change (eg, "Diagnosis as a Watershed") and narratives of a maintenance of self-description (eg, "Unchanged Coping Style").
2. *Type of Coping Style*: the *y* axis probably refers to a continuum between emotional-relational coping styles (eg, "Emotional-relational Coping Style") and instrumental coping styles (eg, "Diagnosis as a Watershed").

We deeply explored FCR through framework analysis of last question (Q5). Although the number of utterances included in the analysis was not significant for a cluster analysis, we elicited at least three relevant themes at t_0. The reported themes are different patterns of adjustment to FCR that frequently overlapped:

1. *Worry Pattern*: FCR is described as a ubiquitous worry that never ends and leads the person to a sort of loss of control ("I seem to go crazy"). Worrying about the future, and especially about the next follow-up, frequently is linked to cognitive alarm, physical hyperarousal, and anxiety ("I think I will never stop worrying about cancer").
2. *Hopelessness Pattern*: this pattern refers to a sense of hopelessness that seems to maintain FCR through a process of depressive rumination and a sense of impossibility to live differently ("you cannot escape, it's like a presence").
3. *Present-Past Pattern*: this refers to a pervasive process of rumination that seems to be characterized by a depressive component ("whenever I try to be happy, I remember what I have become") and, especially, by a post-traumatic component ("that day everything changed as soon as I looked into his eyes"). FCR seems to be activated and maintained by a continuous reappraisal of the past events of illness narrative.
4. *Acceptance Pattern*: the last pattern is composed of all of the sentences related to the process of accepting FCR as a constraint of present life ("it's something you have to deal with"). Such a process is difficult ("it's like a burden you must try not to notice") and different from denial ("I try to go on and dedicate myself to my life").

We assumed that two main dimensions can shape the narrative space of these patterns. The continuum may be considered in terms of psychological severity:

1. *Metacognitive Deficit*: this refers to type and severity of metacognitive deficit that seems to emerge from patients' narratives. The recurrence of processes such as worry, rumination, and so on may lead to a reduced ability in understanding one's own (eg, "I do not know how I found myself crying") or another's (eg, "nobody can understand what I feel") mind.[32]
2. *Maladaptive Coping:* when confronting with the demanding challenge of FCR persons may develop and apply maladaptive coping strategies. Such strategies are defined in terms of perpetuating the personal burden ("if I never think about cancer, I'll finally be fine") and reducing the ability of confronting ("it's better not to talk about how I am with my husband") one's own and other's mental states.[15]

Finally, we compared the answers with Q5 between t_0 and t_1. In t_1, we found a higher recurrence of the Acceptance Pattern in comparison with t_0. The other patterns were present at different levels of quantitative recurrence and qualitative relevance, even though researchers observed a relevant reduction over time. The answers also corroborated an average reduction of psychological severity with respect to Metacognitive Deficit and Maladaptive Coping dimensions.

4 | DISCUSSION

We opted for a mixed-methods approach in order to maximize the collected information about the patients' personal experiences.

According to a paired sample *t* test, the quantitative data seems to highlight a significant reduction of distress, anxious, depressive, and post-traumatic symptoms and a significant increase of mindful awareness between initial (t_0) and second (t_1) assessment ($P < 0.001$). RMANOVA confirmed these results by reporting a significant time effect for all of the outcomes with an effect size ranging from 0.601 to 0.960. Pairwise comparisons and RMANOVA also validated the maintenance of these results at follow-up with the exception of post-traumatic symptoms, which reported a decrease between t_1 and t_2. We may hypothesize a long-term effect of NET component.[37]

RMANOVA separately confirmed MACS' effectiveness in the two subgroups. It is interesting to note that we neither find a significant reduction of distress in either of the two interventions nor an increase of mindful awareness in the group intervention. This is probably due to a low sample size.

The qualitative analyses reported three significant themes: unchanged coping style, emotional-relational coping style, and diagnosis as a watershed. These clusters can be better understood through the hypothesized dimensions of the relative Euclidean space. The narratives seem to be defined by the presence of the coping style's change (or stasis) after the diagnosis and by the continuum between an emotional relational and a more instrumental coping strategy, where the latter is frequently associated with stressful experiences. These results may confirm the need for a program aimed at offering specific interventions for different levels of psychopathological severity and for subjective coping styles.

When exploring the construction of FCR, we found four different patterns that seem to highly overlap within the personal narratives. The comparison between t_0 and t_1 probably highlighted the effectiveness of the interventions, since we reported an increase of acceptance and a reduction of metacognitive dysfunction. The narratives of FCR are probably channeled by different metacognitive deficits[32,33] and maladaptive coping[15] and refer to different impairments connected in turn to different systems (see Figure A1).

4.1 | Clinical implications

MACS is based on the assumption that (a) FCR is a multidimensional process that may be better understood as an adaptive attempt to adjust to life-after-treatment; (b) an intervention for FCR should focus on both psychosocial symptoms and the metacognitive and interpersonal factors maintaining these symptoms. MACS yearns to offer an integrated MBCT program aimed at promoting an adaptive adjustment to FCR by increasing acceptance, mindful compassion, and metacognitive awareness. It adds to the MBCT program different components so as to support patients' strategies in dealing with FCR. We also maintain that the willingness to receive psychosocial support may benefit from differentiated approaches.[38,39] Therefore, we outlined two different interventions.

4.2 | Limitations

The sample size represents the main limitation, as 106 participants do not enable a significant comparison across all possible permutations of participants' features (eg, cancer stage), especially considering that MACS is composed of two different interventions. Additionally, the lack of randomization affects the generalizability of the results. Finally, the absence of a validated Italian measure of FCR forced us to indirectly explore this variable.

5 | CONCLUSION

The present paper describes a prospective single-arm study aimed at evaluating the suitability and the effectiveness of a novel mindfulness- and metacognition-based intervention for women with breast cancer in follow-up care. The research represents a mixed-methods pilot-study, the limitations of which, including scarce sample size and lack of randomization, do not allow for generalizability of the results.

Nonetheless, when considering the specific aims of the research, we report encouraging results in terms of suitability (drop-outs less than 10%) and effectiveness in reducing distress, anxious, depressive, and post-traumatic symptoms ($0.601 > \eta < 0.960$). Moreover, the narratives about FCR seems to be changed over time with an increasing prevalence of acceptance.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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