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Original Research

A longitudinal evaluation of the impact of the COVID-19 pandemic on a cohort of patients treated with clozapine

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Abstract

Objectives: We previously demonstrated that three months into the COVID-19 pandemic, the impact on individuals with treatment-resistant psychotic disorders was modest. Here, we examined and compared the psychological and social impact of the COVID-19 pandemic on the same patient cohort 12 months after their initial study engagement.

Methods: Semi-structured interviews were conducted with 54 individuals (85.7% response rate) between June 12 and July 29, 2021, 12 months after their initial interviews. Participants' subjective experience of the impact of the COVID-19 pandemic on anxiety symptoms, social and vocational functioning was measured utilising the same Likert scales at both time points. Anxiety symptoms were additionally measured using subjective (Beck Anxiety Inventory) and objective (Hamilton Anxiety Rating Scale (HARS)) psychometric instruments. Paired *t*-tests or Wilcoxon ranked tests compared parametric or non-parametric data over time. Free-text responses pertaining to participants' perspectives on the impact of COVID-19 were grouped into themes.

Results: A minor increase in anxiety symptoms was demonstrated utilising the HARS (1.9 points, $z = 3.017$, $p = 0.003$), with a minimal increase in depressive symptoms noted using Likert ratings (0.8 points, $z = 2.119$, $p = 0.034$). Five themes were identified with the most prevalent being (i) positivity regarding vaccination, (ii) social isolation from family members and (iii) looking forward to post-COVID-19 'normality'. However, negative views pertaining to the psychosocial impact of COVID-19 and vaccination were additionally reported.

Conclusions: No significant overall clinical change in symptomatology or functioning over time was noted.The study demonstrated that positive views regarding vaccination and optimism for the future were evident for some participants.

Keywords: Anxiety; clozapine; COVID-19; schizophrenia; vaccination

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Introduction

COVID-19 is the infectious disease associated with the coronavirus SARS-CoV-2 and its' variants. First identified in Wuhan, China, in December 2019, COVID-19 was declared a global pandemic by the World Health Organisation (WHO) on March 11, 2020 (World Health Organisation, 2020). The declaration of the pandemic was followed by widespread implementation of restrictions and 'lockdowns' in many countries worldwide. In Ireland, these restrictions included 'cocooning' of individuals over 70 years of age, as well as those immunologically vulnerable, limitations on travel and the introduction of 'social distancing' measures. This resulted in the closure of many facilities deemed as non-essential. In addition to restaurants and cafes, this included facilities attended by individuals with mental health disorders such as day hospitals and day centres. From May 2020, there have been periods of gradual easing and re-implementation of restrictions, largely based on the advice of the National Public Health Emergency Team, based on a five-level system. The impact of these prolonged periods of restrictions and lockdowns for individuals with psychotic disorders, including treatment-resistant psychotic disorders, remains unclear.

Previous viral pandemics have been associated with an increase in psychosocial distress (WHO 'Outbreak Communication Guidelines', (2005). Studies in individuals without pre-existing mental health disorders (including in Ireland) in relation to the COVID-19 pandemic note an increase in psychiatric pathology, including higher levels of depressive and anxiety symptoms (Wang *et al.*, 2020; Hyland *et al.* 2020). We previously demonstrated a relatively modest deleterious psychological impact of COVID-19 for individuals with pre-existing anxiety disorders (Plunkett *et al.* 2020; Hennigan *et al.* 2021) and bipolar disorder (McLoughlin *et al.* 2021) with social functioning most impacted; however, individuals with a diagnosis of Emotionally Unstable Personality Disorder demonstrated greater symptomatology (McLoughlin *et al.* 2021). Relatively limited research to date has assessed the impact of the COVID-19 pandemic on individuals with pre-existing treatment-resistant psychotic disorders.

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However, some studies that have included individuals with a range of diagnoses including schizophrenia (Rohde *et al.* 2020; Lasevoli *et al.* 2020) noted increased levels of distress and anxiety symptoms secondary to the COVID-19 pandemic. We previously demonstrated only a modest impact on anxiety and depressive symptoms, three months into the COVID-19 pandemic and its' associated restrictions, in a cohort consisting solely of individuals with treatment-resistant schizophrenia attending a clozapine clinic. However, reduced supports both within the community and mental health services were described by some participants (Fahy *et al.* 2021). Consequently, in this study we wanted to assess the psychological and social impact of COVID-19 including its associated mandated social restrictions on the same patient cohort longitudinally. We hypothesised that participants would have increased symptomatology and impaired social functioning compared to initial assessments 12 months earlier. We felt that this was relevant particularly given continued disruption to support both within the mental health services (i.e. closure or reduced input from day centres, reduced group and community activity including group therapy sessions, and reduced face-to-face consultations with treating clinicians) and outside mental health services (i.e. reduced attendance at social events and group therapy sessions organised by other agencies such as AWARE as well as reduced engagement with family and other social contacts).

Methods

Participants

All patients who previously engaged in a study examining the impact of the COVID-19 pandemic on patients with treatment-resistant psychosis attending a clozapine clinic ($n = 63$) (Fahy *et al.* 2021) were invited to participate in this study by letter and subsequently phoned to provide clarification regarding the purpose of and procedure associated with this study. As detailed previously, all individuals were over 18 years of age, had capacity to provide written informed consent for study participation and were treated with clozapine for treatment-resistant psychosis. Participants were excluded if they fulfilled criteria for an intellectual disability (intelligence quotient <70) or had a confirmed diagnosis of dementia. Research interviews were undertaken by one author (AR) with training in study procedures provided by the principal investigator (BH). All collected data were anonymised and securely store and handled in accordance with the Data Protection Act, 2018. Ethical approval was obtained prior to the study commencement from the Galway University Hospitals Research Ethics Committee (C.A. 1462).

Procedure

All individuals previously provided written informed consent, and consent was re-attained verbally for this study. For individuals providing informed consent for engagement in the follow-up study ($n = 54$, 85.7% response rate), clinical case notes were reviewed to ascertain if there were any changes relating to their clinical management, including changes in prescribed psychotropic medications and dosage.

Assessments

A semi-structured interview was conducted either by telephone ($n = 48$) or in-person ($n = 6$) with participants by the same researcher (AR) between June 9th and July 29th, approximately 12 months after their initial engagement with the study (Fahy *et al.* 2021) (see Appendix 1 for details). Demographic and clinical variable data attained in this study related to physical health status including COVID-19 diagnosis and testing status, the effect of COVID-19 on the participants' employment or vocational status and/or site of employment and details pertaining to vaccination for COVID-19 including vaccine type and number. Categorical data pertaining to the effect of COVID-19 on participants' mental health status overall and severity of anxiety symptoms (better, no change, worse) were attained. Participants' subjective experience of the impact of the COVID-19 pandemic on their mental health was measured utilising the same Likert scales at both time-points (1–10) to measure: 1) anxiety symptoms, 2) mood symptoms, 3) social functioning, 4) occupational functioning and 5) quality of life, with 0 indicating no adverse impact and 10 indicating a very severe impact due to the restrictions imposed due to the COVID-19 pandemic. Participants' subjective experience of the impact of being vaccinated (or views regarding vaccination for those not fully vaccinated or who had refused vaccination at the time of interview) against COVID-19 was also measured using these study-specific Likert scales (0–10) to measure: 1) anxiety symptoms, 2) mood symptoms, 3) social functioning, 4) occupational functioning and 5) quality of life, with 0 indicating no beneficial impact of vaccination on symptoms and 10 indicating a very strong beneficial impact of vaccination on symptoms.

The same established psychometric instruments were also used to measure current symptomatology: 1) Beck Anxiety Inventory (BAI, Beck & Steer, 1993) and the 2) Hamilton Anxiety Rating Scale (Ham-A, Hamilton, 1959). The BAI and HARS have previously been utilised and validated for use in individuals with psychotic disorders (Smith *et al.* 2021; Soraya *et al.* 2007). The rationale for using two psychometric instruments (BAI, HARS) was to measure both subjective and objective symptoms of anxiety, increasing the accuracy of the recording of symptoms and reducing any scale bias to increase confidence in results pertaining to anxiety symptoms of this patient cohort.

Free-text data were also collected which enabled participants to clarify the impact that the COVID-19 pandemic and associated restrictions had on their mental health and overall social and psychological functioning.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) 27.0 for Windows (SPSS Inc., IBM, New York, USA). Descriptive analyses (frequencies, percentages, means and standard deviation) on key demographic and clinical data were performed for both categorical and continuous variables, as appropriate. We utilised the paired *t*-test for parametric data to compare psychometric data between baseline and follow-up visits. Data were examined to determine if normally distributed by visual inspection utilising histograms and by Q-Q plots and non-parametric testing were additionally undertaken as appropriate, with the Wilcoxon ranked test utilised (with median and interquartile ranges also attained) to compare data between both time points. The chi-square ($\chi 2$) test was also used for some non-parametric data as appropriate.

Free-text data were examined and were open-coded based on the framework of the questionnaire and on any other themes unrelated to these questions that emerged. This data attained from free texts were then grouped into themes by consensus of the researchers (AR, EMcM, BH).

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Results

Demographics and clinical data

Of the 63 participants initially invited to participate, 5 were uncontactable (i.e. not answering phone calls, attending their local GP rather than the clozapine clinic during COVID-19) and 4 refused to participate, resulting in an 85.7% response rate. Data for the 54 study participants are presented in Table 1. Of note, 38 (70.4%) participants were male and the mean age of participants was 35.5 ± 10.5 years. Fifty (92.6%) participants had a diagnosis of schizophrenia, and the mean duration of clozapine treatment was 11.96 ± 6.91 years. Forty-six (85.4%) participants were fully vaccinated, and a further six (11.1%) were awaiting their second vaccination at the time of interview. Twenty individuals (40.8) stated that the COVID-19 pandemic had a deleterious impact on their mental health, but less participants reported a deterioration in anxiety symptoms ($n = 13$, 26.5%), with only three (5.6%) individuals requiring an increase in their clozapine dose during the study time frame.

Clinical effects of COVID-19

A minor increase in anxiety symptoms measured objectively (HARS) ($z = 3.017$, $p = 0.003$), (mean of 1.87 points), was noted with a similar but non-significant increase (mean of 0.9 points) in subjective anxiety symptoms (BAI) also demonstrated ($z = 1.872$, $p = 0.061$). Likert scale data noted a minor increase in depressive symptoms of 0.82 points ($z = 2.119$, $p = 0.034$), but no other differences were evident between both time points. Social difficulties were associated with the highest score across both time points (see Table 2).

Likert scale examining views regarding vaccination were neutral or positive (median of 5.0 or 6.0) for each scale and mean scores ranging from 4.68 to 5.74 (see Table 2).

Qualitative data

Forty-two (77.78%) participants provided free-text responses when asked if they would like to provide additional comments regarding their thoughts or feelings pertaining to the COVID-19 pandemic. In total, five themes emerged: (1) looking forward to a return to normality ($n = 19$), (2) positive impact of COVID-19 ($n = 15$), (3) positive views regarding vaccination ($n = 12$), (4) negative impact of COVID-19 ($n = 5$), and (5) negative views regarding being vaccinated ($n = 7$) (Box 1). These comments are highlighted in Box 1.

Discussion

To our knowledge, this is the first longitudinal study examining the impact of the COVID-19 pandemic and its restrictions on those with treatment-resistant psychotic disorders. A modest deleterious impact of COVID-19 was noted subjectively when views of overall mental health were examined. Compared to a year earlier, a minimal increase in anxiety symptoms was noted objectively with a similar minimal increase in depressive symptoms noted. However, patients were predominantly positive in their responses regarding vaccination as noted both with Likert scale data and qualitative comments. Free-text responses were also noted relating to a positive impact of the COVID-19 pandemic on their mental health and a positive outlook relating to the complete easing of mandated restrictions.

Table 1. Demographic and clinical data

Variables	*n* (%)
Gender	
Male	38 (70.4)
Female	16 (29.6)
Marital status	
Single	40 (74.1)
Married/partnered	12 (22.2)
Divorced/separated	2 (3.7)
Employment	
Unemployed	37 (68.5)
Employed	16 (29.6)
Retired	1 (1.9)
Domiciliary status	
Parents	16 (29.5)
Other family members	3 (5.7)
Partner/spouse	11 (20.4)
Housemates/friends	4 (7.4)
Group-home	7 (13)
Alone	12 (22.2)
Primary diagnosis	
Schizophrenia	50 (92.6)
Schizoaffective disorder	4 (7.4)
Smoking status	
Current	22 (40.7)
Ex-smoker	4 (7.4)
Non-smoker	28 (51.9)
COVID-19 vaccination status	
Fully vaccinated	46 (85.2)
Partially vaccinated	6 (11.1)
Un-vaccinated	2 (3.7)
Pandemic overall effect on anxiety levels ($n = 49$)	
No change	25 (51)
Better	11 (22.4)
Worse	13 (26.5)
Pandemic overall effect on mental health ($n = 49$)	
No change	26 (53.1)
Better	3 (6.1)
Worse	20 (40.8)
Clozapine dose-change since June 2020 ($n = 54$)	
No change	42 (77.9)
Increase	3 (5.6)
Decrease	9 (16.7)
	Mean (SD)
Age	35.5 (10.5)
Clozapine	
Duration of treatment	11.96 (6.906)
Current clozapine dose	320 (132.7)

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Table 2. Psychometric scores pertaining to the impact of COVID-19 and vaccination for COVID-19

Variable	*n*	Baseline: Mean (SD)	Follow-up: Mean (SD)	Difference (95% CI)	Statistics: *z*, *p*
BAI**	48	7.10 (8.49)	7.73 (6.4)	−0.63, (−2.04, 0.79)	1.872, 0.061
HARS**	47	6.36 (6.72)	8.23 (5.17)	−1.87 (−3.37, −0.37)	3.017, 0.003
Likert scales – impact of COVID-19**	54				
Anxiety symptoms		3.61 (2.95)	3.59 (2.88)	0.02 (−0.75, 0.05)	0.025, 0.980
Depressive symptoms		3.02 (2.4)	3.83 (2.79)	−0.81 (−1.52, −0.11)	2.119, 0.034
Social functioning		3.63 (3.39)	3.89 (2.97)	−0.26 (−1.03, 0.51)	0.630, 0.529
Occupational functioning		2.22 (3.35)	2.67 (3.20)	−0.26 (−1.02, 0.29)	1.209, 0.227
Quality of life		2.96 (3.08)	3.07 (2.74)	−0.11 (−062, 0.40)	0.049, 0.961
Likert scales – vaccination*	46	–		–	–
Anxiety symptoms			5.60 (2.49)		
Depressive symptoms			5.74 (2.44)		
Social functioning			4.68 (2.45)		
Occupational functioning			4.85 (2.43)		
Quality of life			5.37 (2.50)		

*Higher scores reflect reduced anxiety and depressive symptoms and increased social or occupational functioning and an improved quality of life secondary to vaccination.
**Non-parametric (Wilcoxon Signed Rank test utilised) for statistical analysis.

Box 1. Thematic Analysis

Theme 1: Looking forward to a return to normality (*n* = 19)

- "I had been doing a lot of volunteering before COVID and I really want to get back to that" (#2, Female)
- "I miss going shopping in town and I am looking forward to indoor dining coming back" (#6, Female)
- "I'm bored . . . I just want normality. This feels never-ending" (#16, Male)

Theme 2: Positive Impact of COVID-19 Lockdowns (*n* = 15)

- "Everything being closed made my life less intense, there is less social stress" (#10, Female)
- "My anxiety actually decreased, because I didn't have to be around other people as much" (#21, Male)
- "I found it to be a nice break" (#32, Female)
- "I have had lots of time to practice my musical instrument and am getting better at that" (#54, Male)

Theme 3: Positive views regarding vaccination (*n* = 12)

- "I feel a lot less at risk now on busses and in town" (#9, Female)
- "The vaccine makes it easier to get support from my family" (#20, Female)
- "I'm delighted to have the vaccine, I'm always afraid another big outbreak is around the corner" (#32, Female)

Theme 4: Negative Impact of COVID-19 and Lockdowns (*n* = 9)

- "I sometimes feel that I'm immune to stress, but this long-term lack of interaction can't be good for anyone" (#35, Male)
- "I feel very lonely" (#48, Female)
- "I miss the support of my family. Lockdown makes everything feel more far-away" (#47, Male)

Theme 5: Negative views regarding being vaccinated (*n* = 7)

- "I didn't take the vaccine. I'll wait to see what effects it has first" (#19, Male)
- "I felt the vaccine was obligatory" (#34, Male)
- "I got it because I had a duty to my neighbourhood, even though I didn't want to" (#54, Male)

An increase in anxiety and depressive symptoms has been demonstrated during the COVID-19 pandemic in individuals without a pre-existing psychiatric diagnosis (Huang *et al.* 2019; Li *et al.* 2020; Hyland *et al.* 2020). Studies examining patients with a range of pre-existing mental disorders but not exclusively schizophrenia have additionally noted modest increases in symptomatology including an increase in anxiety and depressive symptoms and suicidal ideation (Iasevoli *et al.* 2020; Bendau *et al.* 2021; Hennigan *et al.* 2021; Robillard *et al.* 2021; Rohde *et al.* 2020) although these findings have not been universally demonstrated (Tundo *et al.* 2021). No studies to date have longitudinally examined the impact of COVID-19 exclusively on individuals with treatment-resistant psychotic disorders; however, a small systematic review of patients with schizophrenia noted no exacerbation of psychotic symptoms (Caponnetto *et al.* 2021). The current study notes only a very minor increase in anxiety symptoms with the majority of patients, noting that the COVID-19 pandemic did not have a deleterious impact on their mental health or anxiety symptoms, with this supported by both quantitative and qualitative data. However, there was variability in findings, which is reflective of a recent study of individuals with a range of mental health disorders, who noted no overall change in symptomatology secondary to the COVID-19 pandemic but demonstrated an increase for some participants in symptomatology (Ahrens *et al.* 2021).

There are several putative reasons why individuals with treatment-resistant psychotic disorders may not experience an overall deterioration in symptomatology and functioning. This cohort, despite the severity and longevity of their mental disorder, demonstrated relative stability, with only three individuals requiring an increase in their dose of clozapine during the 12-month period between interviews. This may relate to ongoing support from their community mental health team with face-to-face input from the dedicated clozapine clinic, despite a reduction in the availability of some community supports. Additionally, this patient cohort, unlike individuals without a pre-existing mental disorder experiencing *de novo* symptomatology, has a greater awareness of their access to supports and techniques to reduce distress due to their long-term engagement with the mental health services. Furthermore, this cohort, due to their diagnosis, would likely have a relatively narrow repertoire of activities, as evidenced by only 30% of participants in active employment. Consequently, restrictions secondary to the pandemic have not significantly impacted their routine or social lives. Indeed, potentially due to the presence of negative symptoms in this patient cohort, some patients – as

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evident from the qualitative analysis – viewed the mandatory restrictions with subsequently increased isolation in a positive light. An increase in negative symptoms and in particular asociality has been demonstrated in individuals with schizophrenia in a recent study (Strauss *et al.* 2021), which is potentially reflected in some of the patients' comments in this study. A diagnosis of a mental disorder, including treatment-resistant psychotic disorder, does not mitigate against an individual's ability to be resilient. It is likely that many participants in this cohort have solidified appropriate coping mechanisms and are also demonstrating significant resilience ('positive adaptation, or the ability to maintain or regain mental health, despite experiencing adversity' Herman *et al.* 2011).

Participants in this study demonstrated high rates of vaccination, a finding in contrast to previous studies in Israel (Tzur Bitan, 2021*a*, 2021*b*), where lower rates of vaccination were evident for individuals diagnosed with schizophrenia, particularly for males and for those over 60 years of age. A probable reason for high rates of vaccination in our cohort relates to the additional support provided by the mental health services in Ireland to support individuals with major mental health disorders (i.e. inpatients, attending day services, in receipt of clozapine or long-acting injectable antipsychotic medications) in receiving vaccines at the earliest opportunity given concerns for higher rates of COVID-19 related severe morbidity and mortality in these patient cohorts (Li *et al.* 2020; Tzur Bitan, 2021*b*). It is also apparent that study participants were predominantly very optimistic about the beneficial impact of vaccination as evidenced in most of the qualitative comments. Others felt, however, that they were being vaccinated out of a sense of responsibility to others or perceived they had little choice but to be vaccinated.

There are a number of limitations for this research. This study only included a cohort of patients treated with clozapine, which may not be representative of all individuals with psychotic disorders. Other studies have demonstrated higher rate of comorbid anxiety disorders, especially social anxiety disorder and obsessive-compulsive disorder, in patients with schizophrenia with a prevalence of 38% reported by Temmingh & Stein (2015). Given that only 11.1% of the patient cohort in this study had a pre-existing comorbid anxiety disorder, this needs to be taken into account as a potential limitation. Consequently, caution is required in interpretation of findings for all individuals with schizophrenia. However, to date, no other longitudinal studies have been conducted in this patient cohort. Given the time limitations on interview durations during the pandemic, aiming to keep the length below fifteen minutes, this study did not explore the impact of COVID-19 on psychotic symptoms; however, only three participants had the doses of clozapine increased during the course of this study, with no patients, to our knowledge, requiring an inpatient admission due to a relapse of their psychotic disorder, suggesting that no significant exacerbation in psychotic symptoms was demonstrated. A healthy control group was not included in this study for comparative purposes. Finally, Likert scale data have not been validated, and assessing the subjective impact of the COVID-19 pandemic on mental health symptoms would not be expected to provide identical scores to an assessment on a psychometric scale. However, we believe that the validity of our findings is supported by a moderate correlation (and statistically significant finding) between anxiety symptoms secondary to the COVID-19 pandemic and scores on the BAI ($r = 0.47$, $p < 0.001$) and HARS ($r = 0.42$, $p < 0.001$).

Conclusion

This longitudinal study demonstrated that approximately 15 months into the COVID-19 pandemic and its mandated restrictions, the impact on individuals with treatment-resistant psychotic disorders attending a clozapine clinic has been relatively modest. No significant overall clinical change in symptomatology or functioning was noted over time. Despite some variability in both quantitative and qualitative findings, positive views were demonstrated regarding vaccination with optimism for the future evident.

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Conflict of interest. None.

Ethical standards. Ethical approval was attained from the Galway University Hospitals Research Ethics Committee (C.A. 1462; granted January 7th, 2021). The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committee on human experimentation with the Helsinki Declaration of 1975, as revised in 2008.

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Contributions. All authors participated in the design of the study, data attainment and critical review of the manuscript.

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Appendix 1: Likert Scale Data

COVID-19

Place a number in the box that best describes how the COVID-19 Virus has affected you

0 = No Effect

10 = Severe Effect

Anxiety levels	0	1	2	3	4	5	6	7	8	9	10
Mood Symptoms	0	1	2	3	4	5	6	7	8	9	10
Functioning: Social	0	1	2	3	4	5	6	7	8	9	10
Functioning: Occupation	0	1	2	3	4	5	6	7	8	9	10
Quality of Life	0	1	2	3	4	5	6	7	8	9	10

Additional comments:

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Vaccination

Place a number in the box that best describes how you believe that vaccination for COVID-19 will benefit you

0 = No impact

10 = Significant beneficial effect

Anxiety levels	0	1	2	3	4	5	6	7	8	9	10
Mood Symptoms	0	1	2	3	4	5	6	7	8	9	10
Functioning: Social	0	1	2	3	4	5	6	7	8	9	10
Functioning: Occupation	0	1	2	3	4	5	6	7	8	9	10
Quality of Life	0	1	2	3	4	5	6	7	8	9	10

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